REPORT TO THE PRESIDENT AND CONGRESS ON THE THIRD ASSESSMENT OF THE NATIONAL NANOTECHNOLOGY INITIATIVE

Executive Office of the President

President's Council of Advisors on Science and Technology

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PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY
WASHINGTON, D.C. 20502

March 25, 2010

President Barack Obama
The White House
Washington, DC 20502

Dear Mr. President,

We are pleased to send you this "Report to the President and Congress on the Third Assessment of the National Nanotechnology Initiative," prepared by the President's Council of Advisors on Science and Technology (PCAST). This report reflects a PCAST decision to advise you on this topic and fulfills PCAST's responsibilities under the 21st Century Nanotechnology Research and Development Act (Public Law 108-153) and Executive Order 13349 to provide periodic updates to Congress.

To provide a solid scientific basis for our recommendations, the Council assembled a PCAST Working Group of three PCAST members and 12 non-governmental members with broad expertise in nanotechnology. The Working Group addressed the requirements of Public Law 108-153, with additional efforts aimed in four areas: NNI program management; the outputs of nanotechnology; environment, health, and safety research; and the vision for NNI for the next ten years. The Working Group's deliberations were informed by discussions with 37 government officials, industry leaders, and technical experts from a wide range of fields involving nanotechnology.

The report finds that the NNI—which has provided $12 billion in investments by 25 Federal agencies over the past decade—has had a "catalytic and substantial impact" on the growth of the U.S. nanotechnology industry and should be continued. Further, the report finds that in large part as a result of the NNI the United States is today, by a wide range of measures, the global leader in this exciting and economically promising field of research and technological development.

But the report also finds that U.S. leadership in nanotechnology is threatened by several aggressively investing competitors such as China, South Korea, and the European Union. In response to this threat, the report recommends a number of changes in Federal programs and policies, with the goal of assuring continued U.S. dominance in the decade ahead.

The full PCAST discussed and approved this report, pending modest revisions that have now been completed, at its most recent public meeting on March 12, 2010. We appreciate your interest in this important field of work and sincerely hope that you find this report useful.

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The President's Council of Advisors on Science and Technology

Executive Report

The National Nanotechnology Initiative 2010 Third Assessment along with Recommendations of the National Nanotechnology Advisory Panel

The National Nanotechnology Initiative (NNI) is the U.S. Government's crosscutting program that coordinates Federal research and development (R&D) activities in nanoscale science, engineering, technology, and related efforts among various participating agencies. The Federal Government launched the NNI in FY 2001 with an initial $500 million budget to accelerate the development of nanotechnology. Over the ensuing 10 years, with cumulative Federal spending of $12 billion, the NNI has played a key role in positioning the United States as the world leader in both nanotechnology R&D and commercialization. The NNI has also catalyzed State activities that leverage Federal investments with a focus on economic growth and job creation. Indeed, nanotechnology appears slated to become an important contributor to the economic growth of the United States over the coming decade and beyond.

Today, the NNI is a multi-agency initiative that now includes 25 Federal agencies, 15 of which in FY 2011 will have their own individual budgets for nanotechnology R&D. The NNI is managed within the framework of the National Science and Technology Council (NSTC), the Cabinet-level council by which the President coordinates science and technology policy across the Federal Government. The Nanoscale Science, Engineering, and Technology (NSET) Subcommittee of the NSTC coordinates the planning, budgeting, program implementation, and review of the NNI. The National Nanotechnology Coordination Office (NNCO) provides technical and administrative support to the NSET Subcommittee, serves as a central point of contact for Federal nanotechnology R&D activities, and engages in public outreach on behalf of the NNI. The NNCO also serves as a liaison to academia, industry, professional societies, foreign organizations, and others to exchange technical and programmatic information. Additionally, the NNCO coordinates preparation and publication of NNI interagency planning, budget, and assessment documents, and maintains the NNI Web site, www.nano.gov.

The 21st Century Nanotechnology Research and Development Act of 2003 (Public Law 108-153) calls for a National Nanotechnology Advisory Panel (NNAP) to periodically review the Federal nanotechnology R&D program, that is, to review the NNI. The President's Council of Advisors on Science and Technology is designated by Executive Order to serve as the NNAP. PCAST's first review of the NNI was issued in 2005, the second in 2008.

In this report, PCAST, serving in its role as the NNAP, assessed the effectiveness of the NNI over the past two years and since its inception. PCAST's observations, conclusions, and recommendations presented here are based on the analysis of its 2010 NNI Working Group, consisting of 3 PCAST members and 12 additional nongovernmental experts in nanotechnology. The Working Group's deliberations were informed by discussions with government officials, industry leaders, and technical experts from the wide range of fields affected by nanotechnology. Before beginning its review, the Working Group co-chairs received input from the other members of PCAST, relevant Congressional committee staff, and staff from the Government Accountability Office (GAO), Office of Management and Budget (OMB), the National Research Council (NRC), and OSTP. Based on that input, the Working Group decided that there were three overarching categories that would prove most useful for assessing NNI performance and for arriving at valuable and actionable recommendations to ensure that NNI can succeed in the many roles it has to play. Those categories are:

1. **Program Management**—An appraisal of how well NNI leadership has performed with respect to the roles it has been tasked to carry out.
2. **Nanotechnology Outcomes**—An analysis of what the Federal nanotechnology investment has delivered and recommendations to enhance the outcomes, especially economic outcomes.
3. **Environment, Health, and Safety (EHS)**—An assessment of NNI's performance in helping to orchestrate the identification and management of potential risks associated with nanotechnology, with particular attention paid to reviewing progress the NNI has made in following through on recommendations made in the 2008 NNAP review of the NNI.

Because 2010 marks the tenth anniversary of the NNI, the panel decided it would be appropriate to conclude with a forward-looking chapter that discusses how nanotechnology might contribute to important societal needs and goals in the coming years.

Program Management

In its review of program management, the NNAP determined that the NNI has distinguished itself during its first decade as a successful cooperative venture, now involving the participation of 25 Federal agencies. The NNAP believes that the NNI has been well organized and managed, but that there are several steps that OSTP can take to enable the NNI over the next decade to fully exploit the opportunities offered by the development of nanoscience and nanotechnology, particularly in regard to commercialization efforts.

More specifically, the NNAP believes that the NNI would benefit by OSTP designating more resources for the NNCO to coordinate activities across the NNI and by authorizing dedicated funding of approximately $5 million annually (0.3 percent of agency contributions to NNI funding) to support that mission. A strengthened and suitably funded NNCO should be the coordinating agency to ensure several desirable improvements in managing the NNI, including:

- Enhancing communications with the business community;
- Facilitating technology transfer;

- Providing information on available nanotechnology resources to both the public and private sectors. The NNI has created outstanding resources for the nanotechnology R&D community through its investments in infrastructure such as shared user facilities, research centers and networks, and education centers and networks. Accessible information on these facilities and coordination of their use would ensure optimal leverage of these considerable investments;
- Collaborating with stakeholders on enabling programs such as metrology; standards including size, shape and composition of nanomaterials, and databases of physical and chemical properties of nanomaterials; and manufacturing safety; and
- Engaging in closer and more frequent interactions with state initiatives, which could provide important leverage of resources for the NNI.

In addition, the NNAP believes that as programs are developed within the NNI, the NNCO should track relevant metrics to measure the outcomes and impacts of NNI programs. To assess systematically the outcomes of NNI investment, it would be desirable, for example, to be able to measure the value of all products with nanotechnology components, as well as the value of those components. Following both of these measures over time would give a reasonable picture of the importance of nanotechnology in the economy. Such measurements would in turn enable an estimate of the number of jobs created by nanotechnology, as well as the social rate of return to NNI investment. Rather than relying on funding agencies for such estimates, it would be most appropriate to lodge responsibility with a statistical agency such as the Bureau of Economic Analysis in the Department of Commerce.

A strengthened NNCO will be better positioned to monitor metrics that assess the NNI's impact, such as on job creation, commercial activity, private sector investment including venture funding, advanced degrees, international competitiveness, and the development of methodology for assessing plausible risks associated with nanotechnology.

Program Management Recommendations

Strengthen the NNCO

The NNCO should broaden its impact and efficacy and improve its ability to coordinate and develop NNI programs and policies related to those programs. OSTP should facilitate these improvements by taking the following actions:

- Require each agency in the NNI to have senior representatives with decision-making authority participate in coordination activities of the NNI.
- Strengthen the NNCO to enhance its ability to act as the coordinating entity for the NNI.
- Mandate that the NNCO develop metrics for program outputs and that it works with the Bureau of Economic Analysis to develop metrics and to collect data on the economic impacts of the NNI.
- Appoint two individuals to the NNCO to lead interagency coordination of efforts in the areas of EHS research and standards development, respectively.
- Dedicate 0.3 percent of NNI funding to the NNCO to ensure the appropriate staffing and budget to effectively develop, monitor and assess NNI programs.

Focus on Commercialization

In a budget planning process coordinated by OSTP, each agency should continually re-evaluate its NNI balance of investments among the Program Component Areas (PCAs), with an enhanced focus on commercialization, which would include maintaining the current level of investment in research and doubling the investment in nanomanufacturing (PCA5) over the next five years.

Signature Initiatives

Each Signature Initiative's lead agency should develop coordinated milestones, promote strong educational components, and create public-private partnerships to leverage the outcomes of the Initiatives. Each lead agency also should develop strategies for monitoring, evaluating, and disseminating outcomes.

Education

The agencies of the NNI should continue making investments in innovative and effective education, and the NNCO should consider commissioning a comprehensive evaluation of the outcomes of the overall investment in NNI education.

Societal Impacts

The NSET Subcommittee should develop a clear expectation and strategy for programs in the societal dimensions of nanotechnology. An effective program in societal implications would have well-defined areas of focus, clearly articulated outcomes as well as plans for assessing and evaluating those outcomes, and partnerships that leverage the value of its activities. Ultimately, the inclusion of such programs in the NNI has the goal of streamlining nanotechnology innovation and its positive impact on society, and the creation of new jobs, opportunities and a robust economy.

Nanotechnology Outcomes

The NNAP's review of the NNI's outputs concluded that the NNI has played a critical role in promoting interest and advances in nanotechnology both within the United States and abroad. The United States is clearly the world's leader in nanotechnology R&D and commercialization based on research funding, total number of papers in the most significant scientific publications, patents filed and granted, private sector funding for new and existing companies developing nanotechnologies, and sales of nanotechnology-based products. However, foreign competitors, particularly China, South Korea, Germany, and Japan, are making gains on many of these same metrics. China in particular has significantly increased its share of nanotechnology research publications and patents and now supports nanotechnology as a larger fraction of its total scientific research compared to the United States.

One area in which the United States is unchallenged is in educating nanotechnology researchers. The United States still trains the majority of Ph.D. students in nanoscience and nanotechnology, and though many of these students wish to remain in the United States after completing their degree programs, the data show that over one-third of these students return to their home countries and contribute to the development of nanotechnology R&D programs throughout the world.

To maintain the Nation's leadership role in nanotechnology, the NNAP recommends that the NNI increase its emphasis on nanomanufacturing and commercial deployment of nanotechnology-enabled products, and that the agencies within the NNI must interact and cooperate more with one another to ease the translation of scientific discovery into commercial activity. And though there are benefits to training nanotechnology researchers that return to their home countries, the NNAP also recommends that the Federal Government take steps to retain scientific and engineering talent trained in the United States by developing a program to provide U.S. Permanent Resident Cards for foreign individuals who receive an advanced degree in science or engineering at an accredited institution in the United States and for whom proof of permanent employment in that scientific or engineering discipline exists.

Nanotechnology Outcomes Recommendations

Nanomanufacturing and Commercialization

The National Science Foundation (NSF), Department of Energy (DOE), Department of Defense (DOD), National Institute of Standards and Technology (NIST), and National Institutes of Health (NIH) should include a greater emphasis on manufacturing and commercialization while maintaining or expanding the level of basic research funding in nanotechnology. Specifically, over the next five years, the Federal Government should double the funding devoted to nanomanufacturing (PCA5). In addition, the Federal Government should launch at least five government-industry-university partnerships, using the Nanoelectronics Research Initiative as a model. The Federal Government should also support at least five Signature Initiatives over the next two to three years, with each Signature Initiative funded at levels adequate to achieve its stated goals, presumably between $20 million and $40 million annually.

Nanotechnology Outcomes Recommendations (continued)

Job Creation

The Department of Commerce and the Small Business Administration should advise the NNI on how to ensure that its programs create new jobs in the United States, including coordinating with State efforts, and economic impact should be an explicit metric in the second decade of the NNI.

Workforce Retention

Congress and the Administration need to take steps to retain scientific and engineering talent trained in the United States by developing a program to provide U.S. Permanent Resident Cards for foreign individuals who receive an advanced degree in science or engineering at an accredited institution in the United States and for whom proof of permanent employment in that scientific or engineering discipline exists.

Moving Nanotechnology To Market

The DOE, DOD, NIST, NIH, National Cancer Institute (NCI), and Food and Drug Administration (FDA) should clarify the development pathway and increase their emphasis on transitioning nanotechnology to commercialization, including making sustained meaningful investments in focused areas to help accelerate technology transfer to the marketplace.

Environment, Health, and Safety

In reviewing the NNI's role in addressing EHS issues, the NNAP concluded that the proactive approach to addressing potential EHS impacts of nanotechnology taken by NNI is commendable. By creating jobs, stimulating economic growth, and providing solutions to some of the toughest challenges facing humankind, nanotechnology has great potential to change the world for the better. Yet realizing this potential may be thwarted if the safety of new materials and products arising from nanotechnology is not addressed up front. In the absence of sound science on the safe use of nanomaterials and of technologies and products containing them, the chance of unintentionally harming people and the environment increases. At the same time, uncertainty and speculation about potential risks threaten to undermine consumer and business confidence.

Over the past two years, the NNI has released a cross-agency nanotechnology EHS research strategy, instigated multi-stakeholder workshops on nanotechnology EHS issues, and seen the Federal nanotechnology EHS research budget increase from $67.9 million in 2008 to a requested $116.9 million in 2011. Individual agencies have also played an active role in international efforts to develop nanotechnology responsibly. Even so, significant EHS-related barriers still stand in the way of effective, sustainable, and responsible commercialization of nanotechnology. As the NNI continues to work toward "a future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society," the NNAP recommends that member agencies increase coordinated efforts to overcome these barriers. Specifically, the NSET Subcommittee's interagency working group

on Nanotechnology, Environmental, and Health Implications (NEHI) should develop clear principles to support the identification of plausible risks associated with the products of nanotechnology. The NSET Subcommittee's NEHI working group should also further develop and implement a cross-agency strategic plan that links EHS research activities with knowledge gaps and decision-making needs within government and industry to make commercial and regulatory decisions that ensure safe use of nanotechnology products.

The NNAP also recommends that the NSET Subcommittee implement organizational changes that support consequential cross-agency action on addressing nanotechnology EHS issues. In particular, the NNCO should create a senior-level position to lead interagency coordination of efforts in the area of EHS. Finally, the NSET Subcommittee's NEHI working group should develop publicly-available information resources on cross-cutting nanotechnology EHS issues that are relevant to businesses, health and safety professionals, researchers, and consumers.

Environmental, Health, And Safety Recommendations

Risk Identification

The NSET Subcommittee's NEHI working group should develop clear principles to support the identification of plausible risks associated with the products of nanotechnology.

Strategic Planning

The NSET Subcommittee's NEHI working group should further develop and implement a cross-agency strategic plan that links EHS research activities with knowledge gaps and decision-making needs within government and industry.

Information Resources

The NSET Subcommittee's NEHI working group should develop information resources on crosscutting nanotechnology EHS issues that are relevant to businesses, health and safety professionals, researchers, and consumers.

Organizational Changes

The NSET Subcommittee and OSTP should foster administrative changes and communications mechanisms that will enable the NNI to better embrace the EHS issues associated with nanotechnology research, development, and commercialization.

- The NSET Subcommittee co-chairs should assign an individual to NNCO to oversee interagency efforts that address nanotechnology EHS.
- OSTP and the NSET Subcommittee should expand the charter of the NEHI working group to enable the group to address cross-agency nanotechnology-related policy issues more broadly.
- The NSET Subcommittee should explore mechanisms that enable the NSET Subcommittee's NEHI working group to more effectively receive input and advice from nongovernment experts regarding nanotechnology-related risks.

Action Items

The overall conclusion of this review is that the NNI has had a catalytic and substantial impact on the field and should be continued. The NNAP has concluded that the NNI has been, and continues to be, effective in leading and coordinating the United States' effort in nanotechnology. To ensure that the NNI achieves as much if not more in its second decade as it did during its first, the Working Group developed a number of recommendations, listed in the sections above, for consideration by PCAST. While PCAST endorses all of these recommendations, four of these are of special importance. PCAST, in its role as the NNAP, proposes that the President and Congress:

1. Increase funding for the NNI to ensure that the United States retains its leadership role in the development and commercialization of nanotechnology in the face of mounting competition from countries that have responded to the example set by the NNI by investing significant resources in nanotechnology R&D. Over the next five years, the Federal Government should double the funding devoted to nanomanufacturing, Program Component Area 5 (PCA5). In addition, the Federal Government should launch at least five government-industry-university partnerships, using the Nanoelectronics Research Initiative as a model. The Federal Government should also support at least five Signature Initiatives over the next two to three years, with each Signature Initiative funded at levels adequate to achieve its stated goals, presumably between $20 million and $40 million annually. This funding should be directed primarily to agencies such as the NSF, NIST, DOD, DOE, and NIH. At the same time, the NNI should maintain or expand the level of funding devoted to basic nanotechnology research.

2. Direct the agencies within the NNI to increase the percentage of their nanotechnology related funding provided to the NNCO from $3 million to $5 million, and to require each agency to task senior representatives with decision-making authority to participate in coordination activities of the NNI. The NNCO will use these funds to, among other activities, appoint two individuals to the NNCO to lead interagency coordination of efforts in the areas of EHS research and standards development, respectively. The NNCO must also more actively and aggressively manage the NNI so that it can respond quickly to emerging opportunities and better coordinate interagency efforts, and it must develop metrics for program outputs.

3. Mandate that the NSET Subcommittee's NEHI working group develop a cross-agency strategic plan that links EHS research activities with knowledge gaps and decision-making needs within government and industry, and that the NNCO create a new senior-level position to hold the participating agencies accountable for implementing this strategic plan. This strategic plan must contain clear principles to support the identification of plausible risks based on realistic expectations of exposure to specific nanomaterials.

4. Develop a program to provide U.S. Permanent Resident Cards for foreign individuals who receive an advanced degree in science or engineering at an accredited institution in the United States and for whom proof of permanent employment in that scientific or engineering discipline exists.

A Vision for the Next 10 Years

In its first 10 years, the NNI has promoted progress on scientific problems of great importance to society. It has increased dramatically the investment in instrumentation, research infrastructure, and expertise. Looking forward 10 years, NNAP envisions a program that builds on these strengths, creating new avenues of investigation based on changing societal needs and as yet unforeseen discoveries. A vibrant and effective NNI will have the following attributes:

- ***Basic research will remain a critical component of the research portfolio***. NNI will continue to provide an organizational structure that promotes crosscutting research that enhances our economic competitiveness. New fundamental discoveries will continue to refresh our ideas of what is possible and provide the foundation for new initiatives.
- ***While basic research continues, there will be increasing focus on integration of components and processes that lead to commercialization.*** For example, integration of nanotechnology-enabled diagnosis, imaging, and therapy will provide superior new methodologies for developing individualized cancer management strategies.
- ***The NNI will play a key role in several Signature Initiatives leveraging targeted interagency efforts to address grand challenges.*** The FY 2011 budget accommodates three grand challenge platforms for nanoscience and nanotechnology: Nanotechnology Applications for Solar Energy, Sustainable Nanomanufacturing, and Nanoelectronics for 2020 and Beyond. These and other bold initiatives will be chosen for their potential to improve quality of life, protect the environment, create jobs, and engage a new generation of scientists and engineers. Among some of the other signature initiatives on which the NNI could partner with industry, academia, and the relevant agencies are regenerative medicine, catalysis, food safety, and threat detection. These initiatives, complemented by a vibrant educational program that focuses on the potential of nanotechnology to help solve societal problems, will excite the imaginations of young people and draw the next generation of scientists and engineers into the field.
- ***The balance of NNI programs will continue to evolve.*** For example, there will be a stronger focus in coming years on fundamental issues related to EHS, an effort that will be coordinated by the NIH, NIST, the Environmental Protection Agency (EPA), and other relevant agencies. Novel means of fabrication with ever finer precision should become the focus of new investments in nanomanufacturing, including modeling and simulation, metrology tools, and the merging of self-assembly with lithography to achieve large scale predictable placement of nanoscale components.

The President's Council of Advisors on Science and Technology

The National Nanotechnology Initiative 2010 Third Assessment and Recommendations of the National Nanotechnology Advisory Panel

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I. Introduction and Charge

Chapter Summary

The Federal Government launched the National Nanotechnology Initiative in FY 2001 with a $500 million budget to accelerate the development of nanotechnology. Ten years later, after spending $12 billion of Federal funds and additional private sector funds, the United States is the world leader in both nanotechnology research and development and commercialization. Furthermore, the future looks bright for nanotechnology to become an important contributor to the economic growth of the United States over the coming decade and beyond. Today, the NNI is the Federal Government's crosscutting program that coordinates Federal R&D activities in nanoscale science, engineering, technology, and related efforts among 25 Federal agencies. The NNI is coordinated within the framework of the National Science and Technology Council, the Cabinet-level council by which the President coordinates science and technology policy across the Federal Government. The National Nanotechnology Coordination Office supports the NSTC Subcommittee as the primary point of contact for the NNI.

The 21st Century Nanotechnology Research and Development Act of 2003 (Public Law 108-153) calls for a National Nanotechnology Advisory Panel to periodically review the Federal nanotechnology R&D program, that is, to review the NNI. The President's Council of Advisors on Science and Technology is designated by Executive Order to serve as the NNAP. PCAST's first review of the NNI was issued in 2005, the second in 2008. **This report represents the third review of the NNI by PCAST in its capacity as the NNAP. To execute the review, the NNAP formed a 15-person working group.** The working group agreed that three overarching categories—program management, nanotechnology outcomes, and environment, health, and safety—would prove most useful for assessing NNI performance and for arriving at valuable and actionable recommendations to ensure that NNI can succeed in the many roles it has to play.

The NNAP recommends that the Administration provide increased support and investment in the NNI as a critical component in the Nation's innovation strategy, with an enhanced focus on commercialization of nanotechnology. Overall, the NNAP has concluded that the NNI has been, and continues to be, effective in leading and coordinating the United States' effort in nanotechnology. No effort this large is perfect, however, and the NNAP has developed a number of recommendations in this document to strengthen and improve the NNI, but the overall conclusion is that the program has had a catalytic and substantive impact on the field and should be continued.

Just over 10 years ago, on January 21, 2000, then President Bill Clinton delivered a speech at the California Institute of Technology in which he adopted the voice of a science-fiction visionary and spoke about nanotechnology:

"Just imagine, materials with 10 times the strength of steel and only a fraction of the weight; shrinking all the information at the Library

of Congress into a device the size of a sugar cube; detecting cancerous tumors that are only a few cells in size. Some of our research goals will take 20 or more years to achieve. But that is why, precisely why…there is such a critical role for the Federal Government."

The National Nanotechnology Initiative was launched with an initial investment of $500 million. Now, as the NNI moves into its second decade, and after the Federal Government has spent $12 billion under the NNI rubric, it is important to review the progress that has been made under this bold initiative. It is also important to project the continued potential that nanotechnology offers to society as well as the new challenges it may bring.

What Is Nanotechnology?

Over the years, many people have tried to define nanotechnology. Here is the definition from the NNI Supplement to the President's FY 2011 Budget:[1]

Nanotechnology is the understanding and control of matter at dimensions between approximately 1 and 100 nanometers, where unique phenomena enable novel applications. Encompassing nanoscale science, engineering, and technology, nanotechnology involves imaging, measuring, modeling, and manipulating matter at this length scale.

A nanometer is one-billionth of a meter. A sheet of paper is about 100,000 nanometers thick; a single gold atom is about a third of a nanometer in diameter. Dimensions between approximately 1 and 100 nanometers are known as the nanoscale. Unusual physical, chemical, and biological properties can emerge in materials at the nanoscale. These properties may differ in important ways from the properties of bulk materials and single atoms or molecules.

The promise and optimism about nanotechnology at the launch of the NNI 10 years ago continues to drive many champions and developers of nanotechnology today. Progress has been made in many areas beyond the three examples President Clinton cited in his speech, but nanotechnology is not just a vision of the future. Some forms of nanotechnology are here already, in common use. Consider these examples:

- **Electronics**—The existing semiconductor industry could be described as the most successful and extensive adopter of nanotechnology to date. Current integrated circuits are based on components and structural features in the 30-nanometer range and in some cases even smaller. These dimensions are at least 1000 times smaller than typical biological cells. Every new laptop and iPod works on chips brimming with these nanoscale features.

1. National Science and Technology Council. February 2010. The National Nanotechnology Initiative –Supplement to the President's FY 2011 Budget, p. 5. Available at www.nano.gov/NNI_2011_budget_supplement.pdf.

- **Energy/fuels/environment**—Catalysts and catalytic processes that depend on specific nanoscale structures to steer chemical reactions contribute to a significant portion of the U.S. gross national product (GNP). The catalyst industry and those industries that rely on catalysis exploit this nanotechnology to provide a wide variety of products, such as liquid fuels and plastics, and to contribute to a cleaner environment, such as through the use of catalytic converters to remove pollutants from automobile exhaust. Additionally, materials for high-power, fast-charging batteries used in many cordless power tools incorporate advanced electrodes whose capabilities depend on deliberately-engineered nanoscale architectures.
- **Medicine**—Several nanoparticulate formulations of conventional drugs are being used in the treatment of cancer and infectious disease. A number of nanotechnology-based imaging agents and therapeutics that target tumor cells and arterial plaques are in clinical trials. In addition, nanotechnology-based detectors form the core of a number of new diagnostic instruments that are better than previous generations of instruments at detecting minute quantities of important biomarkers of disease.
- **Materials**—Carbon nanotubes are currently being incorporated into high-strength composites and woven into yarns to produce significantly lighter and more conductive wires and electrical harnesses.
- **Consumer products**—Nanoscale materials and particles are being used increasingly as ingredients in cosmetics, sunscreens, and food products. The small sizes of the particles confer various properties, such as high sun-blocking power with translucency in sunscreens, stain resistance for fabrics, and self-cleaning properties and better color features for paints.

The National Nanotechnology Initiative

The NNI is the U.S. Government's crosscutting program that coordinates Federal research and development activities in nanoscale science, engineering, technology, and related efforts among various participating agencies. The NNI was established in FY 2001 with an initial budget of $500 million and with six Federal agencies as original participants. Today, the NNI is a multi-agency initiative that includes 25 Federal agencies, 15 of which in FY 2011 have their own individual budgets for nanotechnology R&D. Overall, the budget number and allocation among the NNI's Program Component Areas is determined in a collaborative manner among OSTP, OMB, and the participating agencies. In FY 2010, the budget for 13 agencies totals $1.6 billion. The FY 2011 budget request totals $1.8 billion, and includes increased R&D investments in two PCAs: Nanomanufacturing and Environment, Health, and Safety. The budget request also calls for FDA and the Consumer Products Safety Commission (CPSC) to join the roster of agencies that fund nanotechnology R&D. The cumulative investment in nanotechnology by the Federal Government since the NNI's inception, including the $1.8 billion requested for FY 2011, totals about $14 billion.

The NNI is managed within the framework of the National Science and Technology Council, the Cabinet-level council by which the President coordinates science and technology policy across the Federal

Government. The NSET Subcommittee of the NSTC coordinates the planning, budgeting, program implementation, and review of the NNI. The NSET Subcommittee is composed of representatives from Federal agencies participating in the NNI (see Appendix E).

The NNCO provides technical and administrative support to the NSET Subcommittee, serves as a central point of contact for Federal nanotechnology R&D activities, and engages in public outreach on behalf of the NNI. The NNCO also serves as a liaison to academia, industry, professional societies, foreign organizations, and others to exchange technical and programmatic information. Additionally, the NNCO coordinates preparation and publication of NNI interagency planning, budget, and assessment documents, and maintains the NNI Web site, www.nano.gov.

The December 2007 NNI Strategic Plan[2] reiterated the vision for the NNI: a future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society. The plan specifies the following four goals to achieve the overall vision:

1. Advance a world-class nanotechnology research and development program;
2. Foster the transfer of new technologies into products for commercial and public benefit;
3. Develop and sustain educational resources, a skilled workforce, and the supporting infrastructure and tools to advance nanotechnology; and
4. Support responsible development of nanotechnology that considers the technology's environmental, health, safety, and broader societal dimensions.

National Nanotechnology Advisory Panel

The 21st Century Nanotechnology Research and Development Act of 2003 (Public Law 108-153) calls for a National Nanotechnology Advisory Panel to periodically review the Federal nanotechnology R&D program, that is, to review the NNI. The President's Council of Advisors on Science and Technology is designated by Executive Order to serve as the NNAP. Section 4 of the law states that the Advisory Panel shall advise the President and PCAST on matters relating to the NNI (referred to also as "the program"), including assessing:

- Trends and developments in nanotechnology science and engineering;
- Progress made in implementing the program;
- The need to revise the program;
- The balance among the components of the program, including funding levels for the program component areas;
- Whether the program component areas, priorities, and technical goals developed by the Council are helping to maintain U.S. leadership in nanotechnology;
- The management, coordination, implementation, and activities of the program; and
- Whether societal, ethical, legal, environmental, and workforce concerns are adequately addressed by the program.

2. http://www.nano.gov/NNI_Strategic_Plan_2007.pdf

NNAP's first review of the NNI was issued in 2005;[3] the second one was issued in 2008.[4] A summary statement in the 2008 report about the United States' status in the global nanotechnology R&D movement, which could be an indication of NNI's performance, included the following assessment:

"The United States remains a leader in nanotechnology based on various metrics, including R&D expenditures and outputs such as publications, citations, and patents. However, the European Union has more publications and China's output is increasing."

Regarding the NNI's role and performance in this context, the NNAP stated in their 2008 report, among other things, that:

- The ongoing NNI investment in infrastructure and instrumentation is commended and encouraged;
- Advances in nanotechnology are embodied in a growing number of applications in various industries;
- The approach for addressing EHS research under the NNI is sound;
- In consultation with the President's Council on Bioethics, the panel concluded that at present, nanotechnology does not raise ethical concerns that are unique to the field; and
- NNI continues to be a highly successful model for an interagency program; it is well organized and well managed.

Based on its assessment, the prior NNAP made six recommendations in 2008 to strengthen the NNI. They are paraphrased below:

1. **Infrastructure, management, and coordination**—The NNI should improve the intra-agency coordination, and NNI member agencies should support international coordination through international forums such as the Organisation for Economic Co-operation and Development (OECD).
2. **Standards development**—Federal agencies should continue to engage in national and international standards development activities. A strong U.S. representation should be maintained in international forums and efforts made to avoid duplicative standards work. Where appropriate, NIST and other NNI agencies should develop reference materials, test methods, and other standards that provide broad support for industry production of safe nanotechnology-based products.
3. **Technology transfer and commercialization**—NNI funded centers should be structured to encourage partnering with industry. The NNI should seek means to assess more accurately nanotechnology-related innovation and commercialization of NNI research results

3. www.nano.gov/html/res/FINAL_PCAST_NANO_REPORT.pdf
4. www.nano.gov/PCAST_NNAP_NNI_Assessment_2008.pdf

4. **Environmental, health, and safety implications**—EHS research for nanomaterials should be coordinated with those taking place in industry and with programs funded by other governments to avoid gaps and unnecessary duplication. EHS research should be coordinated with, not segregated from, applications research to promote the coordinated consideration of risks and benefits associated with nanomaterials and technologies incorporating them.

5. **Societal and ethical implications**—Research on the societal and ethical aspects of nanotechnology should be integrated with technical R&D and take place in the context of broader societal and ethical scholarship.

6. **Communication and outreach**—The NNI should expand outreach and communication activities by the NNCO and the Nanotechnology Public Engagement and Communications Working Group and by coordinating existing agency communication efforts. Information should be developed with broad input and should be made available in ways that incorporate two-way communication.

In addition to the two prior NNAP reviews, the NNI is subject to periodic reviews by other Federal and non-Federal panels with appropriate expertise. For example, the 21st Century Nanotechnology Research and Development Act of 2003 directs the National Research Council to conduct a triennial external review of the NNI. The first NRC review was published in 2006. The second triennial review has not been initiated, but it would be useful to have the detailed program review conducted by the NRC to complement this review by the NNAP.

In 2009, the NRC also published a more specific review of the NNI's EHS program, which is discussed in chapter four of this document. As this third NNAP review was being prepared, the NRC was also conducting another EHS study titled "Research Strategy for Environmental, Health, and Safety Aspects of Engineered Nanomaterials."

The GAO currently has a review underway that is examining the current and future uses for manufactured nanomaterials, what is known about potential risks of these materials, and EPA's efforts to understand and regulate these risks. This work is expected to be released in the summer of 2010.

The 2010 Review of NNI by the NNAP

This report represents the third review of the NNI by PCAST in its capacity as the NNAP. To execute the review, the NNAP formed a 15-person working group. The co-chairs and one other member of the working group are members of PCAST. The other members of the working group consisted of external representatives from academia, industry, and nongovernmental organizations (NGOs). In developing the Statement of Task (SOT) and related questions for this review (Appendix A), the co-chairs of the working group received input from the other members of PCAST, relevant Congressional committee staff, and staff from GAO, OMB, NRC, and OSTP (Appendix B).

Two in-person working group meetings were held for preparatory purposes, to obtain input from technical experts (Appendix C) from government, NGOs, academia, and industry; to gather information and discuss issues; and to develop a range of recommendations that were considered by the NNAP. For additional input, experts were asked to answer a series of questions (Appendix B) related to the seven

areas of focus defined by 21st Century Nanotechnology Research and Development Act, as well as a number of additional questions developed by the working group. This process is described in Appendix D.

The NNI review group agreed that there were three overarching categories that would prove most useful for assessing NNI performance and for arriving at valuable and actionable recommendations to ensure that NNI can succeed in the many roles it has to play. Those categories are:

1. **Program management**—An appraisal of how well NNI leadership has performed with respect to the roles it has been tasked to carry out.
2. **Nanotechnology outcomes**—An analysis of what the Federal nano investment has delivered and recommendations to enhance the outcomes, especially economic outcomes.
3. **Environment, health, and safety**—An assessment of NNI's performance in helping to orchestrate the identification and management of potential risks associated with nanotechnology, with particular attention paid to reviewing progress the NNI has made in following through on recommendations made in the 2008 NNAP review of the NNI.

Each of these categories forms the basis of the three chapters that follow. Because 2010 marks the 10th anniversary of the NNI, the panel decided it would be appropriate to conclude with a forward-looking chapter that discusses how nanotechnology might contribute to important societal needs and goals in the coming years.

There are a number of recommendations in this document to strengthen and improve the NNI, but the overall conclusion is that the program has had a catalytic and substantial impact on the field and should be continued. The NNAP recommends that the Administration, through OSTP and OMB, provide increased support and investment in the NNI as a critical component in the nation's innovation strategy with an enhanced focus on commercialization of nanotechnology.

II. Program Management

Chapter Summary

Over the course of its first decade, the NNI has distinguished itself as a successful cooperative venture involving the participation of 25 Federal agencies. The NNAP believes that the NNI has been well organized and managed, but that there are several steps that OSTP can take to enable the NNI over the next decade to fully exploit the opportunities offered by the development of nanoscience and nanotechnology, particularly in regards to commercialization efforts.

In particular, the NNAP believes that the NNI would benefit by OSTP designating more resources for the NNCO to coordinate activities across the NNI and by authorizing dedicated funding of approximately $5 million annually (0.3 percent of agency NNI funding, up from less than 0.2 percent of agency NNI funding, or almost $3 million, in FY 2010) to support that mission. The NNCO will use these funds to, among other activities, appoint two individuals to the NNCO to lead interagency coordination of efforts in the areas of EHS research and standards development, respectively. The NNCO should also conduct regular reassessments of the balance of funding to each of the PCAs. The NNCO should also continue to spearhead efforts in nanotechnology education and develop an overall strategy to guide research on the societal impacts of nanoscience and nanotechnology that include, but also go beyond, EHS issues.

From its inception, the NNI has been distinguished by broad interagency participation that can collectively span the breadth of investments needed to fully exploit the opportunities offered by the development of nanoscience and nanotechnology. Beginning with six agencies at its establishment in 2001, the NNI currently involves the nanotechnology-related activities of 25 Federal agencies, 15 of which have specific budgets to fund R&D in this area.[5] The NNCO acts as the primary point of contact for information on the NNI and provides technical and administrative support for the NSET Subcommittee, the interagency body that coordinates planning, budgeting, and program implementation for the NNI. As a focal point of information about the NNI, the NNCO maintains the NNI website and provides public outreach on behalf of the NNI. At present, the NNCO operates with one Federal employee serving as director via an NSTC agency detail and a staff of six to seven contractors. The current NNCO budget represents less than 0.2 percent (under $3 million in FY 2010) of the NNI total budget and comes from contributions provided voluntarily by the participating funding agencies.

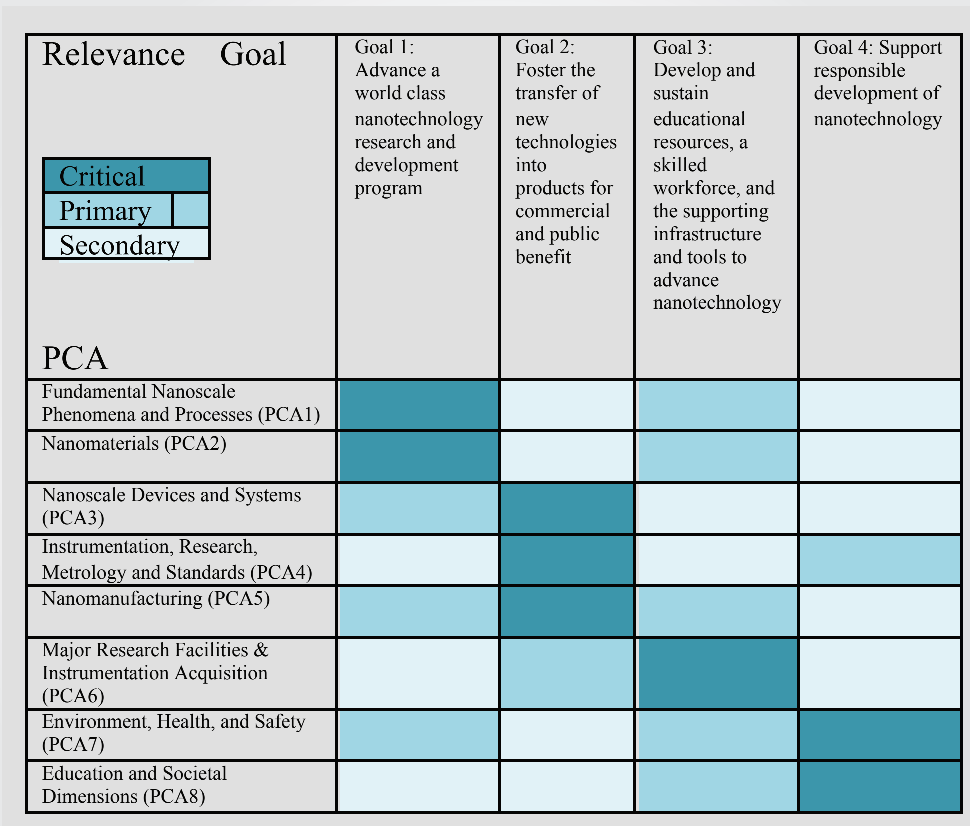
In addition to the four primary goals of the NNI listed in this review's Introduction, the program revised its strategic plan in 2007 to include the following eight specific Program Component Areas:

1. Fundamental Nanoscale Phenomena and Processes
2. Nanomaterials
3. Nanoscale Devices and Systems

5. National Science and Technology Council. February 2010. The National Nanotechnology Initiative –Supplement to the President's FY 2011 Budget, p. 5. Available at www.nano.gov/NNI_2011_budget_supplement.pdf.

4. Instrumentation Research, Metrology, and Standards for Nanotechnology
5. Nanomanufacturing
6. Major Research Facilities and Instrumentation Acquisition
7. Environment, Health, and Safety
8. Education and Societal Dimensions

The PCAs provide an organizational framework for the activities of the NNI and serve to group together related projects and activities. The relationship between the PCAs and NNI goals can be represented by Figure 2-1.



Figue 2-1. Relationships between the picas and NNI goals

Source: NNI 2007 Strategic Plan

Overall, the NNAP believes that the NNI continues to serve as a commendable model of an interagency program that is generally well organized and managed. The goals of the NNI are comprehensive and cogent, the PCAs remain an effective means of tracking the investments in the NNI, and

the working groups[6] of the NSET Subcommittee appropriately provide added interagency focus on crosscutting topics of importance to the NNI and the realization of its goals. However, the NNAP believes that there are ways in which the program management could be further strengthened as the NNI enters its second decade.

Issues for a Maturing NNI: Beyond Year 10

The NNI is in its 10th year of Federal funding, having garnered bipartisan support in an exceptional, long-term commitment to innovation and transformative change. As the NNI matures, and with a range of nanotechnologies primed to move into commercialization and implementation, the need becomes even greater for close interagency coordination, for well-conceived strategies for investments, and for the identification of measurable outcomes for that investment. Also critical is the effective collection and dissemination of information about NNI programs and resources to the broad range of stakeholders. The NNAP thus expects that the NNCO will have an even greater and more critical role to play in communications and coordination among the various participants of the NNI.

RECOMMENDATION 2-1: STRENGTHEN THE NNCO

The NNCO should broaden its impact and efficacy and improve its ability to coordinate and develop NNI programs and policies related to those programs. OSTP should facilitate these improvements by taking the following actions:

- Require each agency in the NNI to have senior representatives with decision-making authority participate in coordination activities of the NNI.
- Strengthen the NNCO to enhance its ability to act as the coordinating entity for the NNI.
- Mandate that the NNCO develop metrics for program outputs and that it works with the Bureau of Economic Analysis to develop metrics and to collect data on the economic impacts of the NNI.
- Appoint two individuals to the NNCO to lead interagency coordination of efforts in the areas of EHS research and standards development, respectively.
- Dedicate 0.3 percent of NNI funding to the NNCO to ensure the appropriate staffing and budget to effectively develop, monitor and assess NNI programs.

To strengthen the decision-making process and implementation of coordinated NNI activities, each NNI member agency should designate senior representatives with decision-making authority to participate in the NSET Subcommittee. With a stronger coordinating body that has the knowledge and authority to formulate and monitor programs, the NNI will be better prepared to take on new strategic initiatives,

6. Working groups on (1) Global Issues in Nanotechnology, (2) Nanotechnology Environmental and Health, (3) Nanomanufacturing, Industry Liaison, & Innovation, (4) Nanotechnology Public Engagement & Communications.

fine tune existing programs, allocate investments in ways that are more responsive to new opportunities and needs, and serve as a communications hub among NNI participants as well as for the public and all stakeholders.

A strengthened NNCO should be the coordinating agency to ensure several desirable improvements in managing the NNI, including:

- Enhancing communications with the business sector;
- Facilitating technology transfer;
- Providing information on available nanotechnology resources to both the public and private sectors. The NNI has created outstanding resources for the nanotechnology R&D community through its investments in infrastructure such as shared user facilities, research centers and networks, and education centers and networks. Accessible information on these facilities and coordination of their use would ensure optimal leverage of these considerable investments;
- Collaborating with stakeholders on enabling programs such as metrology; standards including size, shape and composition of nanomaterials, and databases of physical and chemical properties of nanomaterials; and manufacturing safety; and
- Engaging in closer and more frequent interactions with States, which could provide important leverage of resources for the NNI. The workshops previously held on regional, state, and local initiatives are commendable, but these opportunities should be provided more often for more active ongoing engagement.

In addition, the NNAP believes that as programs are developed within the NNI, the NNCO should track relevant metrics to measure the outcomes and impacts of NNI programs. To assess systematically the outcomes of NNI investment, it would be desirable, for example, to be able to measure the value of all products with nanotechnology components, as well as the value of those components. Following both of these measures over time would give a reasonable picture of the importance of nanotechnology in the economy. Such measurements would in turn enable an estimate of the number of jobs created by nanotechnology, as well as the social rate of return to NNI investment. Rather than relying on funding agencies for such estimates, it would be most appropriate to lodge responsibility with a statistical agency such as the Bureau of Economic Analysis in the Department of Commerce.

The NNCO needs to monitor metrics that assess the NNI's impact, such as on job creation, commercial activity, private sector investment including venture funding, advanced degrees, international competitiveness, and the development of methodology for assessing plausible risks associated with nanotechnology.

To accomplish the range of tasks described above, the NNAP recommends that OSTP increase the set-aside from the NNI budget allocated to the NNCO to 0.3 percent of NNI funding, or about $5 million annually.

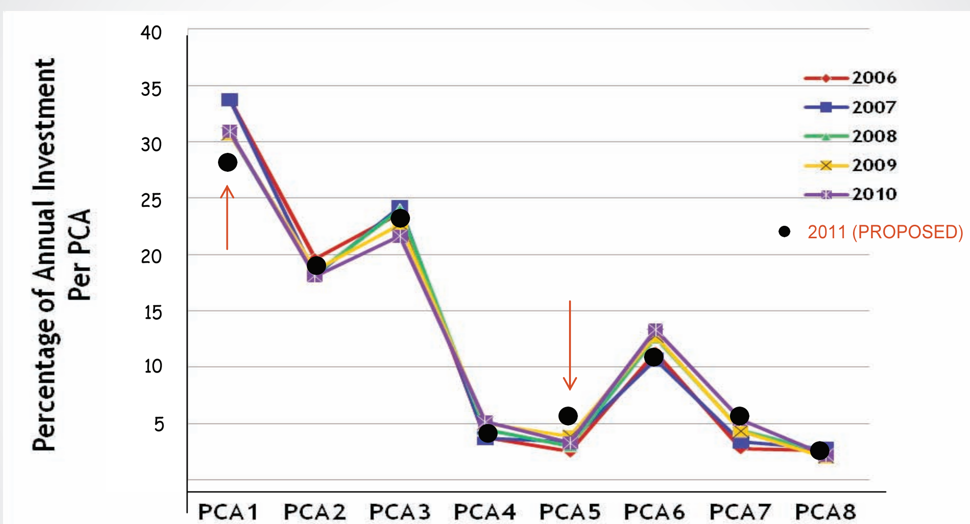
Recommendation 2-2: Focus on Commercialization

In a budget planning process coordinated by OSTP, each agency should continually re-evaluate its NNI balance of investments among the PCAs, with an enhanced focus on commercialization, which would include maintaining the current level of investment in research and doubling the investment in nanomanufacturing (PCA5) over the next five years.

Figure 2-2 tracks the relative NNI investment per PCA from 2006 (when they were initially established) to 2010. The largest percentage investment has been in PCA1 (Fundamental Nanoscale Phenomena). The combined funding for PCA1 and PCA2 (Nanomaterials) has comprised about 50 percent of the total NNI funding; this reflects the importance of investments for fundamental research in nanoscience and nanotechnology, which will underlie further innovation, applications, and potential for commercialization.

Although the amount of requested NNI funding changed from $1 billion in 2006 to $1.64 billion in 2010, Figure 2-2 shows that there has been little change in the distribution among the PCAs over those five years. There has been a small change in distribution in the FY 2011 budget request, allowing for significant increases in Nanomanufacturing (PCA5) of $26 million, or about 34 percent more than 2009. Funding for EHS research (PCA7) increased from $35 million in 2006 to $117 million in the FY 2011 request. Examination of Figure 2-2 suggests that these increased investments were largely offset by a decrease in investments devoted to PCA1; the overall distribution of funds to other PCAs remains similar to those in previous years.

Figure 2-2. PERCENTAGES OF ANNUAL NNI INVESTMENT PER PCA, 2006-2011



Source: C. Teague, Survey (2006-2010) and NNI – Supplement to the President's 2011 Budget. Red arrows indicate the major changes in allocation of the 2011 proposed budget.

The re-examination of the FY 2011 budget and the increased emphasis on nanomanufacturing is laudable. However, it is important to realize that as the programs of the NNI mature, the appropriate percentage investments into the PCAs would be expected to evolve. For example, one might also expect increasing emphasis on Nanoscale Devices and Systems (PCA3) and Metrology and Standards (PCA4), and that different kinds of Major Research Facilities (PCA6) may be needed and appropriate. A continual re-evaluation of investments among all the PCAs is thus important: an increase in funding of nanomanufacturing alone will not provide the full complement of resources required to usher the fundamental R&D fruits of the NNI into phases of commercialization and implementation.

In addition, agencies with Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs should include the PCAs in their planning processes. The NNCO should work with the senior management from each agency to develop the full NNI funding profile, thereby leveraging existing resources and preventing duplications of efforts.

Nanotechnology Signature Initiatives in the Service of Society

The NNAP applauds the introduction of the three Signature Initiatives described in the FY 2011 budget. The NNAP views these three grand challenge platforms for nanoscience and nanotechnology—Nanotechnology Applications for Solar Energy, Sustainable Nanomanufacturing, and Nanoelectronics for 2020 and Beyond—as new opportunities for collaborative involvement of the participating agencies and to define flagship programs for the NNI.

Recommendation 2-3: Signature Initiatives

Each Signature Initiative's lead agency should develop coordinated milestones, promote strong educational components, and create public-private partnerships to leverage the outcomes of the initiatives. Each lead agency also should develop strategies for monitoring, evaluating, and disseminating outcomes.

The NNAP also believes that these initiatives will inspire and attract outstanding students by providing them with opportunities to apply leading edge nanoscience and nanotechnology in the service of society. The success of these Signature Initiatives is particularly important in light of the challenges represented by well-funded and increasingly aggressive overseas nanotechnology programs.

New Knowledge, New Themes, and New Means of Learning

The NNI has distinguished itself in its focus on education and outreach. In particular, funding for National Science and Engineering Centers (NSECs) and Materials Research Science and Engineering Centers (MRSECs) has provided an unusually rich, multi-disciplinary educational environment intrinsic to nanoscience and nanotechnology. The National Center for Learning and Teaching in Nanoscale Science has provided an outstanding resource for students and teachers alike, and the Nanoscale Informal Science Education (NISE) Network has done much to underscore the tremendous efficacy of interactive displays, various forms of dialogue and engagement between scientists and the public, and other informal learning situations.

Recommendation 2-4: Education

The agencies of the NNI should continue making investments in innovative and effective education, and the NNCO should consider commissioning a comprehensive evaluation of the outcomes of the overall investment in NNI education.

Either through the NNI or independently, various master's and Ph.D. programs have been established in nanotechnology. A well-educated workforce and public are critical to the continued prosperity of our society, and these programs should be continued from grades K-12 and beyond. The NNAP urges that the agencies in the NNI continue to seek creative programs that engage and educate broad sectors of the public. The NNAP also recommends strongly that a comprehensive review of such programs be undertaken to better understand what outcomes and benefits have been realized.

Programs in Societal Implications

The inclusion of programs involving the societal implications of nanotechnology, both as part of center-funded initiatives as well as through specifically established Nanotechnology and Society Centers, has been a laudable signature of the NNI. Studies on the societal dimensions of nanotechnology can encompass a broad spectrum of issues: such studies can involve the public perception of research in nanotechnology and its attendant benefits and possible risks, the economic and global aspects of the nanotechnology enterprise, and achieving an understanding of the process of innovation and the path to commercialization.

Recommendation 2-5: Societal Impacts

The NSET Subcommittee should develop a clear expectation and strategy for programs in the societal dimensions of nanotechnology. An effective program in societal implications would have well-defined areas of focus, clearly articulated outcomes as well as plans for assessing and evaluating those outcomes, and partnerships that leverage the value of its activities. Ultimately, the inclusion of such programs in the NNI has the goal of streamlining nanotechnology innovation and its positive impact on society, and the creation of new jobs, opportunities and a robust economy.

As nanotechnology is finding increasing application in a wide range of products and contexts, it is critical that the NNCO develops a clear strategy and focus for this program. A strategic and effective investment in the societal aspects of nanotechnology would define which areas of research to focus on, what outcomes are expected, what partnerships would best guarantee desired outcomes, and how those outcomes are to be evaluated.

III. Outputs of Federal Nanotechnology Research

Chapter Summary

In this chapter, the Working Group reviews the output for the NNI and that of other countries that are developing their own national nanotechnology efforts. This review shows that the NNI has played a critical role in promoting interest and advances in nanotechnology both within the United States and abroad. Though still the leader in nanotechnology R&D and commercialization, the United States is losing ground to foreign competitors, particularly China, South Korea, Germany, and Japan, on a number of key metrics of research output and commercial activity. The United States still trains the majority of Ph.D. students in nanoscience and nanotechnology, but more than one-third of these students do not stay in the United States, even when, in many cases, they wish to stay and when U.S. companies or universities wish to retain them. Having the world's top talent has been critical for the United States' success in nanotechnology, and if this talent continues to move overseas, the economic benefits and job creation will follow."

To maintain our leadership role in nanotechnology, the NNAP recommends that the NNI increase its emphasis on nanomanufacturing and commercial deployment of nanotechnology-enabled products, and that the agencies within the NNI must interact and cooperate more with one another to ease the translation of scientific discovery into commercial activity. The NNAP also recommends that the Federal Government take steps to retain scientific and engineering talent trained in the United States by developing a program to provide U.S. Permanent Resident Cards for foreign individuals who receive an advanced degree in science or engineering at an accredited institution in the United States and for whom proof of permanent employment in that scientific or engineering discipline exists.

In the 10 years since the FY 2001 launch of the NNI, worldwide interest and investment in nanotechnology R&D have soared. Today, virtually every country that supports scientific R&D has a nanotechnology initiative, and some nations are on a path that could lead to serious challenges to the leadership of the United States in the development of nanotechnology-based products. This chapter examines how the NNI is affecting the development of innovative products within the United States and in comparison to the rest of the world, with an eye on assessing how the United States is faring in what is becoming heated competition to reap the fruits of nanotechnology R&D. This chapter also considers current barriers that hinder the transfer of research advances into the marketplace.

Trends and Developments in Nanotechnology Science & Engineering

The NNAP has observed a number of general trends since its last review of the NNI in 2008. Nanotechnology science and engineering is becoming more interdisciplinary and global, with innovation being particularly strong at the intersection of fields. The fundamental science base built over

the past decade is today yielding a rapidly growing number of nanotechnology-based products and companies. This growth has been accompanied by an increasing emphasis on the infrastructure needed to support the commercialization of nanotechnologies and to study potential societal impacts, most notably in the areas of EHS and nanomanufacturing. Matching pace with this growth, funding as a metric of the level of nanotechnology activity has continued to increase as well, with total global funding in 2008 increasing 15 percent to $18.2 billion from $15.8 billion in 2007. The United States' share of the 2008 total was $5.7 billion, up 9 percent from the $5.2 billion that the government, corporations, and venture capitalists invested in nanotechnology in 2007. Government funding in 2008 was 46 percent of total funding, an increase of 16 percent from 2007 levels.[7]

In 2001, the NNI's main focus was to revolutionize the development of microelectronics and new manufacturing technologies. There have been notable successes in this area, such as the development and widespread use of high-resolution lithography. However, new opportunities have also arisen in areas that were nascent or unanticipated at the inception of NNI 10 years ago, and that today could be the focus of "signature initiatives" (some of which are included in the FY 2011 budget request) that would drive the next 10 years of the NNI. These include:

- Nanomedicine (e.g., imaging, diagnostics and therapeutics; antibiotics; gene regulation);
- Nnergy storage, generation, and conversion;
- Environmental diagnostics and cleanup;
- Structural and multi-functional nanocomposites;
- Homeland security (e.g., chemical and biological detection and monitoring); and
- Manufacturing nanotechnology-based products.

During the last several years, basic research on carbon nanotubes, composites, and coatings has declined even as applications of nanotechnology have grown. For example, several companies today are commercializing low-cost carbon nanotubes for use as conductive components, such as in the electrodes in advanced batteries (a company developing novel nanotube-based electrical composites is highlighted later in this chapter). Research on materials such as graphene, metamaterials, silicon nanowire thermoelectrics, and plasmon-enhanced solar cells has increased. About one-third of current nanotechnology research is related to sensors, and nanotechnology research in the life sciences has doubled since 2002.

Moreover, it is recognized that nanotechnology can play a critical role in addressing global problems of energy supply, climate change, and sustainability. Energy and environmental applications of nanotechnology have undergone explosive growth. In 2008, this sector accounted for 29 percent of all nanotechnology funding by the Federal Government, 14 percent of all corporate nanotechnology funding, 41 percent of venture capital funding, 21 percent of nanotechnology publications, and 59 percent of all nanotechnology patents.[8]

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7. Lux Research, "Nanotechnology State of the Market Q1 2009," 2009, Section 4.1.
8. Lux Research, "Nanotechnology State of the Market Q1 2009," 2009.

Since the last NNAP review, a number of commercialization landmarks occurred in nanotechnology:

- The private sector has continued to invest in nanotechnology. Worldwide corporate funding of nanotechnology R&D first exceeded government funding in 2007, and this trend continued in 2008; in the United States, private funding (including corporate R&D and venture capital investments) was more than double the total of Federal nanotechnology funding.[9]
- An estimated $224 billion worth of *final products* sold worldwide made some use of nanotechnology components in 2009, up from $135 billion in 2007. Products made in the United States accounted for $80 billion of the final products, though the share of the global sales attributed to the United States declined from 39 percent to 35 percent.[10]
- The essential nanotechnology *components* (nanointermediates) that went into these products amounted to $29 billion worth of sales; $11 billion worth of these components were made in the United States.
- Among these products, the largest share, 55 percent, was from the materials and manufacturing industry sector, including products such as automobiles, industrial equipment, and building and construction. These products made use of nanotechnology-based components such as coatings, composites, and electronic components. Next, 32 percent of the final products were from the electronics and information technology sector, and included items such as mobile devices with displays and antimicrobial coatings enhanced with nanotechnology. Some 12 percent of nanotechnology-based products were in the healthcare and life sciences sector, primarily from nano-enabled drug delivery systems, while 1 percent of nanotechnology-based products came from the energy and environmental sector and included items such as nano-enabled filtration membranes or batteries.

At the level of individual States, nanotechnology is vibrant and active. Today, some 25 States have their own nanotechnology programs. Most State efforts leverage Federal NNI-supported research by emphasizing translational research and development aimed at state and regional job creation by the private sector. Among the most ambitious of these is the College of Nanoscale Science and Engineering at the State University of New York, Albany. With New York State assistance, the College has built infrastructure consisting of 800,000 square feet of shared new facilities for public-private partnerships. More than a dozen companies involved in the development of nanoelectronics technologies now use this facility.

Assessing U.S. Leadership in Nanotechnology

While the United States continues to lead in most areas, it has lost ground to foreign competitors based on several key metrics. Applicable metrics include the number of scientific publications, citations to published literature, patents, the amount of government and corporate spending, the number of nanotechnology centers and initiatives, the number of Ph.D. graduates, and the number of active companies. The rate of growth in certain of these is especially high for China, South Korea, Germany, and Japan, as this report explains in more detail below.

9. Lux Research.
10. Lux Research, "The Recession's Ripple Effect on Nanotech," 2009.

Research activity as measured by publications and citations—At the time of the last NNAP review in 2008, the United States had lost ground to the 27 nations in the European Union (EU27) in total number of nanotechnology publications[11] and was nearly equal to China (including Taiwan), as shown in Figure 3-1. Since then, the total number of publications from U.S. laboratories has decreased slightly, while the number of Chinese publications has continued to climb. As a result, in 2009 the United States is now third behind China and the EU27 in the total number of nanotechnology publications.

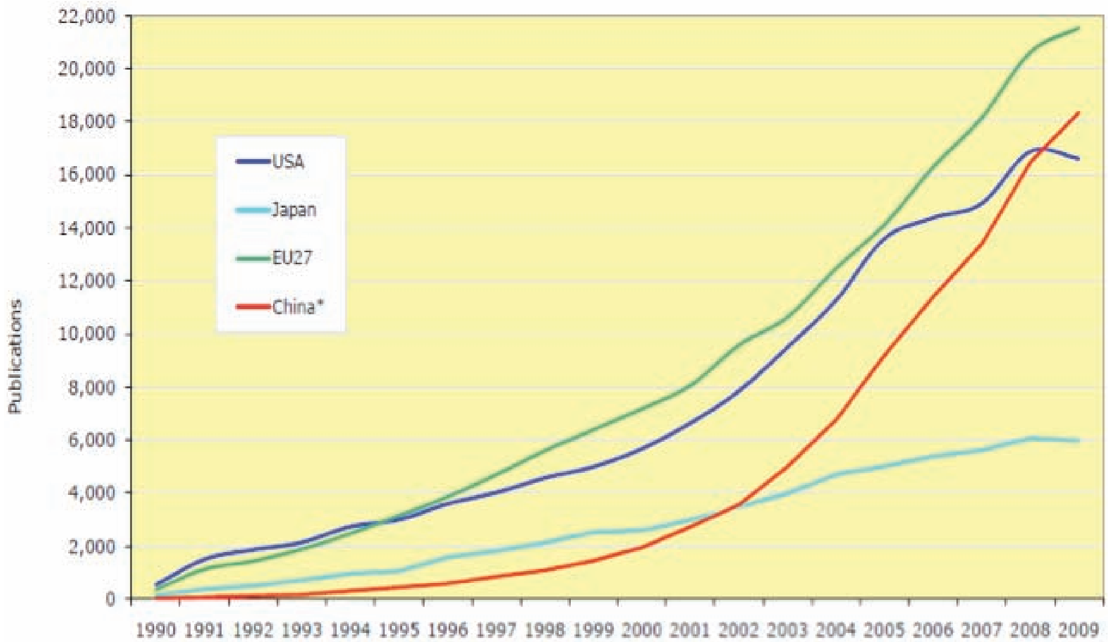


Figure 3-1. Total number of nanotechnology publications appearing in the Science Citation Index by year. Numbers for China include Taiwan.

Source: Chen HC, Dang M, Roco MC. "Updated Nanotechnology Indicators, January 2010." Addendum to Chen H, Roco MC (eds). *Mapping Nanotechnology Innovations and Knowledge: Global, Longitudinal Patent and Literature Analysis*. New York: Springer-Verlag, 2008.

The total number of publications does not necessarily reflect quality or influence, however. Many of the publications from China are not published in the 12 core journals of nanoscience and nanotechnology,[12] while researchers from the United States and the EU27 continue to contribute the majority of papers appearing in those journals. Nonetheless, China's share of publications in these journals is increasing at about the same rate as the United States' share is decreasing, as shown in Figure 3-2.

11. As listed in the Science Citation Index.

12. These 12 are identified by Leydesdorff [*Scientometrics, Vol. 76, No. 1 (2008) 159–167*] as: *Advanced Drug Delivery Reviews, Advanced Materials, Chemistry of Materials, Current Nanoscience, Fullerenes Nanotubes and Carbon Nanostructures, Journal of Nanoparticle Research, Journal of Nanoscience and Nanotechnology, Journal of Physical Chemistry B, Microfluidics and Nanofluidics, Nano Letters, Nanotechnology*, and *Nature Materials*. They do not include *Science*, *Nature*, and Proceedings of the National Academy of Sciences, in which the most highly cited articles in nanoscience appear.

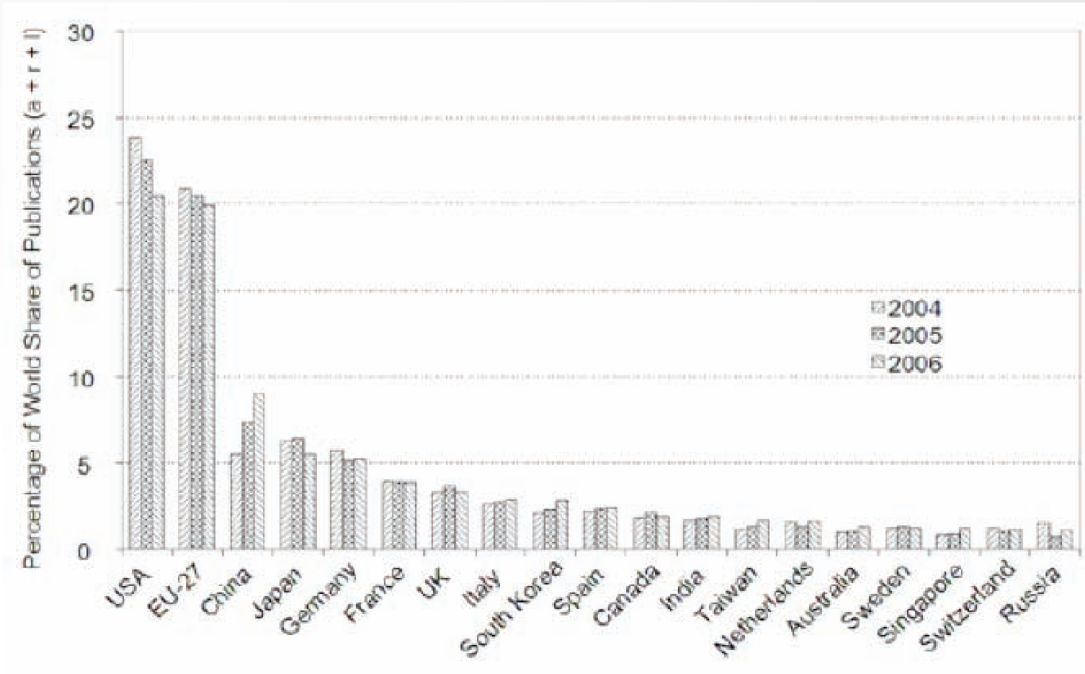


Figure 3-2. Percentage of world share of publications in 12 core journals of nanoscience and nanotechnology by country, for the years 2004-2006.

Source: Leydesdorff L, The delineation of nanoscience and nanotechnology in terms of journals and patents: A most recent update, Scientometrics, 2008; 76(1):159–167

As another measure of publication quality, consider publications in the three journals *Science*, *Nature*, and *Proceedings of the National Academy of Sciences*; papers appearing in these three journals are most often cited in other nanotechnology papers and patents, a measuring of scientific importance. According to this metric, the United States continues to hold a dominant position with about 65 percent of the total number of citations, as shown in Figure 3-3. Nonetheless, the trend since 2005 shows that the percentage of such citations attributed to the United States, France, Germany, and Japan are relatively static, while China's share increased sharply in 2008–2009 and may soon exceed that of France and Japan.

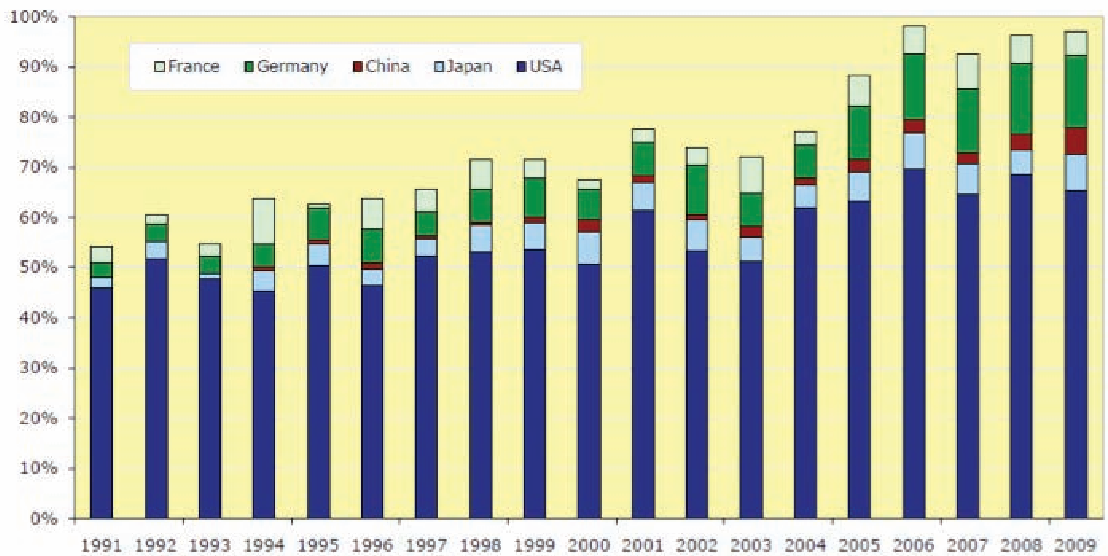


Figure 3-3. Percentage of nanotechnology papers published in *Science*, *Nature*, and *Proceedings of the National Academy of Sciences* that are cited by other publications and patents, organized by country of the research institution.

Source: Chen HC, Dang M, Roco MC. "Updated Nanotechnology Indicators, January 2010." Addendum to Chen H, Roco MC (eds). *Mapping Nanotechnology Innovations and Knowledge: Global, Longitudinal Patent and Literature Analysis*. New York: Springer-Verlag, 2008.

Thus, while the United States remains the leader in scientific publication quality, it no longer dominates in total nanotechnology research output. Moreover, publication trends for other countries indicate a proportionally greater emphasis on nanotechnology. In China, Japan, South Korea, India, Taiwan, and Singapore, nanotechnology research is a larger fraction of all scientific research than it is in the United States.

Patents—Patent activity is a key metric of technology creation. The United States remains the world leader by a large margin in the absolute number of nanotechnology patents *issued*, with more than 1500 nanotechnology patents being issued in each of 2007 and 2008. The total number of nanotechnology patents issued to U.S. inventors since 1995 exceeds 10,000.[13] Germany and Japan are a distant second and third with about 10 times fewer patents issued. However, the number of patents issued is a lagging indicator, while the number of patent applications *filed* is a forward indicator as it typically takes several years for filed patents to issue. As shown in Figure 3-4, patent filing activity in China rose sharply during the period 2000-2004 and overtook the United States during 2005-2008.

13. Lux Research, "Nanotechnology State of the Market Q1 2009," 2009, Section 4.2.

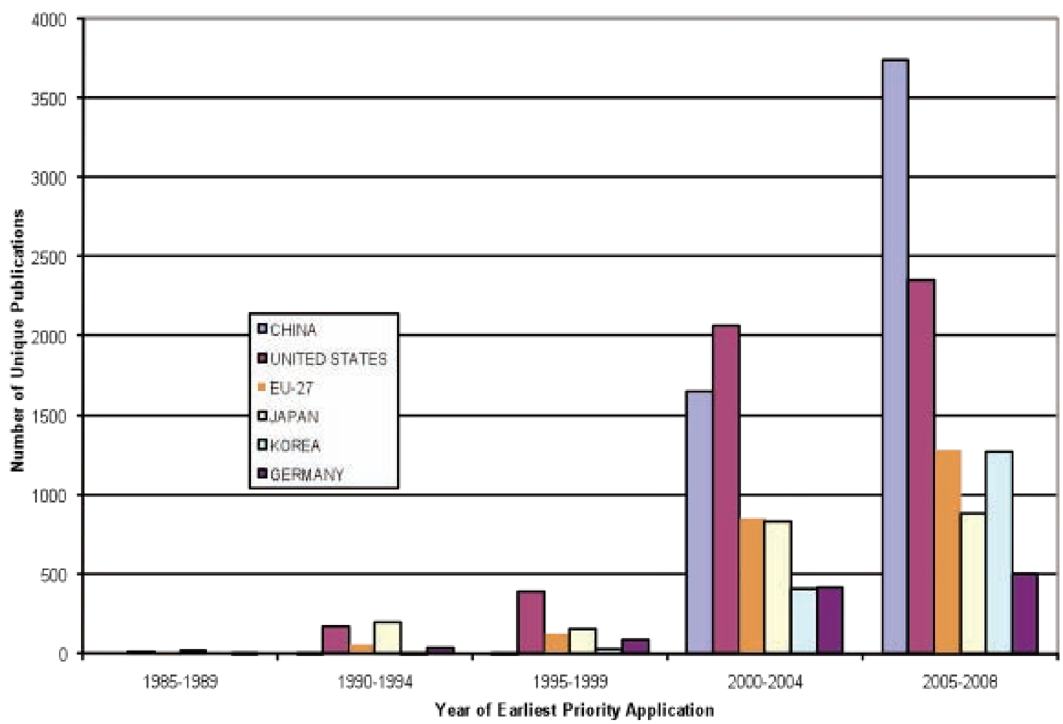


Figure 3-4. Nanotechnology-related patent applications published for the first time, organized by country of the assignee, for different 4-year periods.

Source: Kisliuk B, USTPO, unpublished study on comparative patent filings, January 2010

Another level of analysis examines whether patents are filed internationally versus only in the inventor's home country. This may be viewed as a measure of international impact, although there are other reasons why patents may not be filed internationally, such as the cost of patent prosecution abroad, or when the main market for the technology is in the home country. Of all nanotechnology patents filed internationally (the criteria being in three or more countries) during the 1985-2007 period, about 41 percent have U.S. assignees, while only 1.3 percent have Chinese assignees, as shown in Figure 3-5.

Based on these metrics there are two clear trends in China: Chinese inventors are filing patents at a rapidly increasing rate, and most of these filings are aimed at protecting innovations in their home market. China's patent trends, combined with its expected future economic growth, could afford it widespread nanotechnology protection in one of the world's largest markets in coming decades.

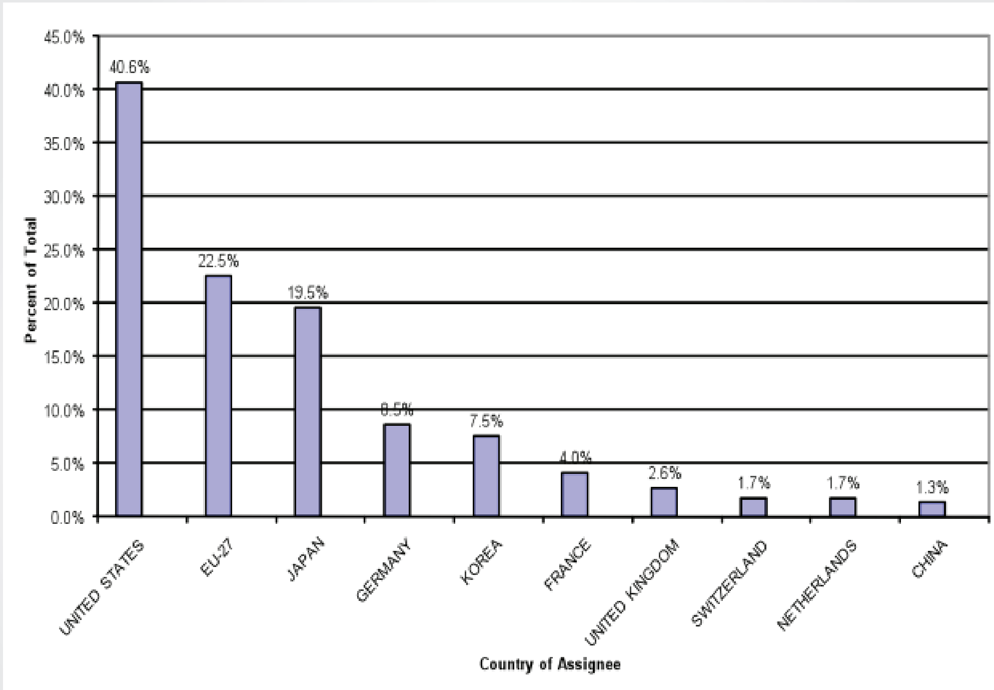


Figure 3-5. Inventions filed in at least three countries, organized by country of the assignee, cumulatively over the years 1985–2007.

Source: Bruce Kisliuk, USTPO, unpublished study on comparative patent filings, January 2010

Dedicated nanotechnology funding. The United States still invests more money in nanotechnology R&D that any other country, with a total of $5.7 billion in investments in 2008, including $1.9 billion from Federal and State governments, $2.7 billion in corporate R&D, and $1.0 billion in venture capital investments. However, as in other areas, the rest of the world is closing the gap, and even surpassing the United States by some metrics. Asia as a region now invests more than the United States, totaling $6.6 billion in 2008. Of the Asian total, Japan leads with $4.7 billion in R&D funding, but with growing contributions from China, South Korea, and other countries, as shown in Figure 3-6. While the U.S. Government funds more R&D than any other individual country, Figure 3-7 shows that total nanotechnology R&D spending by the United States was eclipsed by Europe in 2005 and by Asia in 2007. From 2003 to 2008, total nanotech funding in the United States grew at a compound annual growth rate of 18 percent, while funding in the rest of the world grew at 27 percent annually.

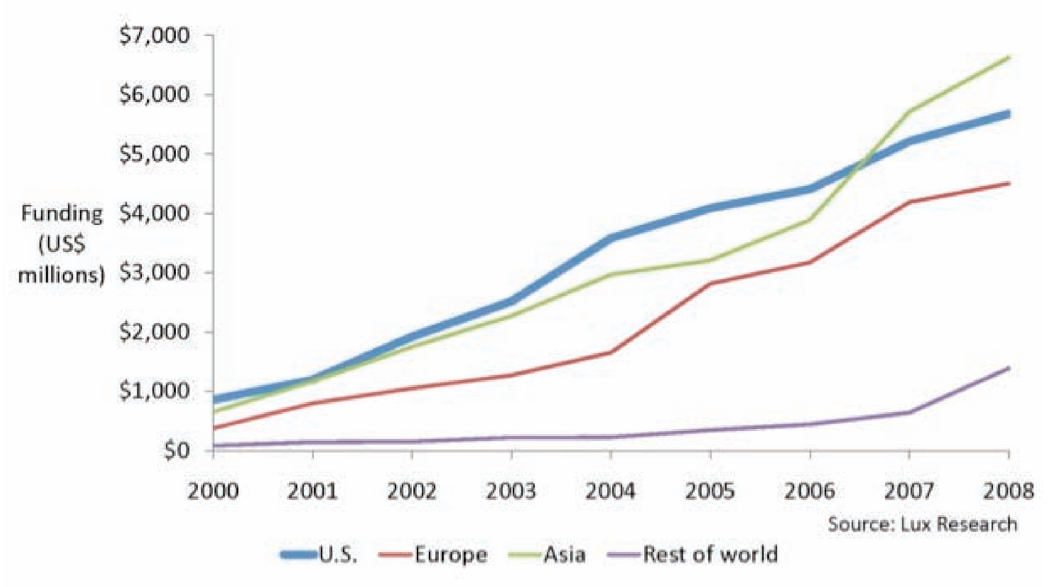


Figure 3-6. Total funding for nanotechnology (from all sources, including government, corporate R&D, and venture capital), plotted by year, shows Asia in the lead since 2006.

Source: Lux Research

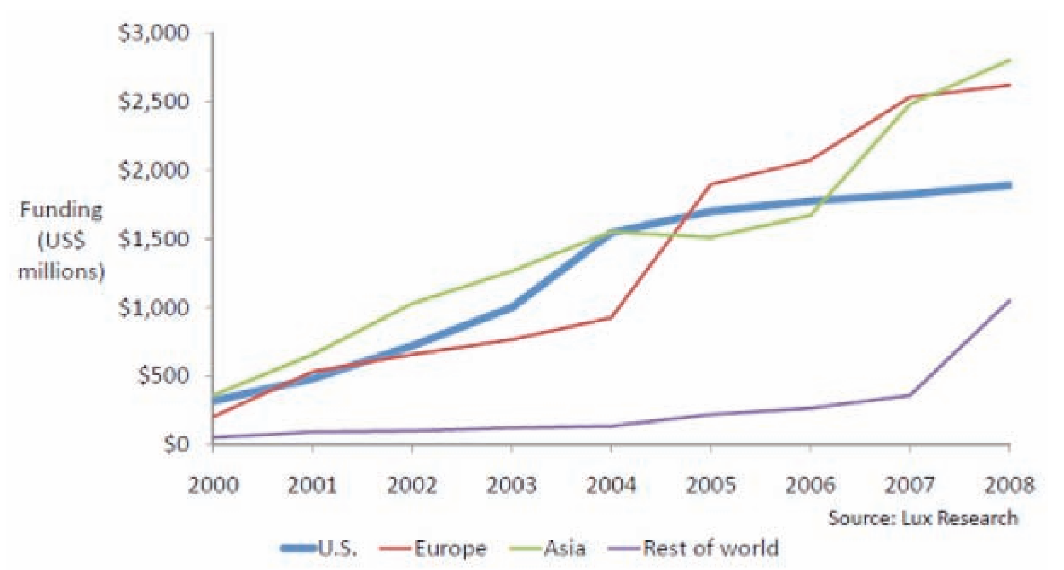


Figure 3-7. Over the same period, government funding in the United States has lagged that in Europe and Asia.

Source: Lux Research

Education and workforce development—Over the course of the past decade, the United States has educated more of the world's science and engineering workforce than any other country, largely through research and development funds provided through the NNI. However, the current rate of retention of highly trained non-U.S. citizens hampers the Nation's ability to capitalize fully on the opportunities created by nanoscience and nanotechnology. Consider the following statistics: From 2004–2007, 26,035 Ph.D. degrees were granted in science and engineering by U.S. universities to citizens from China, South Korea, and India. This figure represents 55 percent of all nonresident Ph.D. degrees, and 18 percent of total science and engineering Ph.D.s in that time period. Of these students, 87 percent indicated intent to stay in the United States after completing their degrees. Ultimately, however, only 57 percent of those indicating such intent remained in the United States. Thus, it can be inferred that on the order of 9,700 of these highly trained individuals were lost to the U.S. workforce during this time. The NNAP believes that the numbers for nanotechnology mirror these for science and engineering as a whole. U.S. national laboratories and companies that must hire U.S. citizens to conduct R&D in certain nanotechnology areas are especially handicapped by a severe shortage of qualified personnel. Relatively few students from foreign countries are naturalized while in graduate school, so the percentage of non-U.S. citizens graduating is probably the same as those entering.

Overall nanotechnology growth—Taking into account the above metrics, as well as the technology development capabilities of nations based on additional factors such as the percentage of gross domestic product (GDP) derived from high technology, R&D spending as a percentage of GDP, and trained workforce development (in addition to education and retention of science and engineering Ph.D.s), the United States remains the leader in nanotechnology R&D. However, Japan, Germany, and South Korea are closing the gap.[14] As of 2008, Japan ranks second with consistent strong investment in corporate R&D and numerous government initiatives. There has been explosive growth of nanotechnology R&D in Germany over the past several years as a result of its own investments combined with significant funding from the European Commission Seventh Framework Programme. In fact, German nanotechnology R&D has now surpassed that of the rest of the European Union. South Korea ranks third in corporate spending on nanotechnology and is perhaps better positioned to capitalize on nanotechnology than any other Asian nation, despite its small relative size. China is poised to capture manufacturing activity in value-added nanomaterials as applications grow and commoditization ensues. It is likely to develop a strong position in the low-cost manufacture of nanomaterials such as carbon nanotubes, nanofibers, and nanopowders. However, China is also improving its capabilities in areas not reliant solely on low-cost manufacturing by ramping up its homegrown scientific research and workforce talent pool. The inescapable conclusion is that the United States cannot assume that it will continue to be the world nanotechnology leader.

Technology Transfer

Nanotechnology is expected to have substantial and long-lasting impact in many areas, including nanoelectronics, healthcare, and clean energy. The electronics industry already manufactures products that involve nanoscience and nanoengineering innovations. Applications in health care (diagnostics, delivery, and discovery) and clean energy technologies (efficiency, storage, and photovoltaics) are developing rapidly.

14. Lux Research, "Nanotechnology State of the Market Q1 2009," 2009, Section 4.2.

All told, U.S. corporations have invested an estimated $2.75 billion in nanotechnology R&D, 50 percent of which was spent by the electronics & information technology sector, 37 percent by the materials and manufacturing sector, 8 percent by the healthcare and life sciences sector, and 4 percent in the energy and environment sector.[15] Most large U.S. corporations in these sectors have established structured nanotechnology efforts over the last decade, though their approaches vary widely from loosely coordinated research initiatives to centralized task forces for mapping nanotechnology's impact.[16] Over the last two years, however, as companies have better understood the potential effect of nanotechnology on their business, their focus has shifted from evaluating nanotechnology as a broad theme to capitalizing on specific nanotechnology opportunities.[17] While large corporations are not often direct recipients of NNI funding, they will often serve as channels to market for nanotechnology-based products. In addition, these large companies rely heavily as sources of nanotechnology innovation and partnerships on the start ups, universities, and national laboratories that do benefit directly from NNI support.[18]

Many nanotechnology innovations are also being developed within start-up companies funded by venture capital (VC). Over the past 10 years, VC investment in U.S. companies developing nanotechnology totals $5.03 billion, accounting for 86 percent of the worldwide VC investments in nanotechnology. VC funding increased dramatically in 2008, reaching $1.15 billion, its highest total ever. However, as a result of the recession and mirroring the pattern in other technology areas, VC funding fell to $667 million in 2009. Over the last two years, VC involvement in nanotechnology was driven increasingly by large investments in later stage rounds for existing companies, as opposed to investments in new firms. The total number of new companies developing nanotechnology in the United States receiving seed or Series A financing in 2008 and 2009 totaled 56, down from 74 in 2006 and 2007. While some of the drop-off reflects the state of the world economy, venture capitalists are increasingly averse to areas of nanotechnology that have long times to market and high capital requirements, thus becoming more selective in their investments.[19] As a result, there is a need for novel approaches and funding mechanisms to support the transfer of technologies with long incubation times from the laboratory to the market.

Some nanotechnology start-up companies have begun to reach liquidity events, initial public offerings (IPOs) or acquisitions that provide returns to their investors. Despite some notable successes, returns to investors from nanotechnology start ups have been mixed. There is still a need for assistance to start ups, not only in bridging the gap from academic research to initial commercial funding (the traditional "valley of death"), but also in transitioning from venture-backed research and product development into the commercial production. It is difficult for venture capitalists and other financiers to earn returns on their investments until their companies begin generating significant revenues and, ideally, profits.

Over the past decade, seven U.S. nanotechnology firms have completed IPOs, with a cumulative value at the time of their IPOs of $3.75 billion. Since the last NNAP review, A123 Systems, a nanotechnology-based battery company, completed a $428 million offering, making it one of the most successful technology IPOs in 2009; the firm is considered a bellwether for the field of energy and environmental technologies.

15. Lux Research, "Nanotechnology State of the Market Q1 2009," 2009, Section 2.
16. Lux Research, "The CEO's Nanotechnology Playbook," 2005.
17. Lux Research, "Nanotechnology State of the Market: Stealth Success, Broad Impact." 2008.
18. Op. cit.
19. Lux Research, "2009 Nanotech Venture Capital: Healthcare and Life Sciences Provide Life Support," 2010.

Mergers and acquisitions (M&A) of nanotech firms have been more common but less lucrative. While 15 nanotechnology start-up companies based in the United States were acquired during the last decade, including six since the last NNAP review, many companies have been sold at a loss. The purchase price for those 15 acquisitions is estimated to total approximately $260 million, compared to $273 million that had been invested into those companies prior to their acquisition. Finally, many nanotechnology start ups have simply gone out of business, including at least 15 VC- backed firms.

In the health sciences, nanotechnology has evolved from early state demonstrations and discovery to a more mature phase in which a portfolio of practical applications is emerging. Here, progress in technology transfer can be assessed by the nanotechnologies expected to have substantial clinical impact. Two areas are particularly relevant:

- **Diagnostics and imaging**—Nanosensors are detecting clinical biomarkers with higher sensitivity and specificity as compared to existing assays. Sensitivities for proteins and nucleic acid detection are quickly moving into the femtomolar and attomolar range, a level previously unobtainable and one that is creating new opportunities for advancing the detection of disease. Imaging is being enabled by new contrast agents that are active in a wide range of clinical modalities, including optical imaging (quantum dots), magnetic resonance imaging (iron oxide particles), and ultrasound (polymeric bubbles). These nanoscale imaging contrast agents are enabling clinicians to view organs at a level of detail that has not been easily obtained until now. Finally, nanostructures such as carbon nanotube electron emitters are being employed to build a new generation of imaging instrumentation that have lower voltage demands, multiplexed emissions sources, and smaller footprints. Some of these new instruments are likely to reduce patient radiation exposure while producing images with enhanced resolution and sensitivity.
- **Therapeutics**—A wide range of nanotechnologies is effectively enabling nearly all phases of drug development. Notably, drug delivery nanotechnology platforms have advanced significantly in the last five years, with increasing capability to deliver drugs to specific organs and cell types. Progress in moving new nanotechnology-based drugs out of the laboratory is significant with a number of clinical trials and Investigational New Drug applications (INDs) filed from investigators funded by the National Institutes of Health. These nanotechnologies are also being placed on a commercialization path, as demonstrated by the numbers of new companies emerging from various areas of nanotechnology supported through NIH. To accelerate the translation of research into clinical advances, the National Cancer Institute and FDA are working together to develop a clear pathway for evaluating and approving a diversity nanotechnology-based diagnostics and therapeutics. Strengthening such interagency coordination is essential for successfully moving nanotechnology from the laboratory into the commercial arena.

Barriers to Commercialization

The NNAP observes that the rate of innovation and the rate of opportunity creation have not decreased over the first 10 years of the NNI, including during the two years since the last NNAP review. However, against the backdrop of immense opportunity, there is also a clear sense, based on metrics such as those discussed earlier, that the United States is losing ground to other countries in the scale up,

commercialization, and industrialization of new nanotechnologies. The NNAP believes that there are a number of significant barriers that hinder the ability of the United States to most effectively capture the benefits of the Nation's nanotechnology research endeavors, which the NNI has worked so hard to promote. The NNAP also believes that there are concrete steps that the NNI can take to reduce or eliminate these barriers.

Recommendation 3-1: Nanomanufacturing and Commercialization

The NSF, DOE, Department of DOD, NIST, and NIH should include a greater emphasis on manufacturing, and commercialization while maintaining or expanding the level of basic research funding in nanotechnology. Specifically, over the next five years, the Federal Government should double the funding devoted to nanomanufacturing (PCA5). In addition, the Federal Government should launch at least five government-industry-university partnerships, using the Nanoelectronics Research Initiative as a model. The Federal Government should also support at least five Signature Initiatives over the next two to three years, with each Signature Initiative funded at levels adequate to achieve its stated goals, presumably between $20 million and $40 million annually.

Successful commercialization of any developing technology requires a healthy ecosystem in which there is continuous innovation at all levels; it cannot simply be based on exploitation of past accomplishments. Fundamental research provides the seed corn for innovation in nanotechnology, without which the pipeline quickly empties. Thus, support for basic research in nanotechnology must not be reduced.

Traditional academic boundaries impede crosscutting research, as do funding silos where particular topical areas are captive to, or perceived to be captive to, single agencies. Since nanotechnology science and engineering is truly interdisciplinary, NNI member agencies should remove obstacles that prevent them from collaborating more. As part of that effort, there should be more interaction among Federal Government funding agencies to remove barriers to multi-agency support during the lifecycle of R&D projects. As an example, organizations that have successfully completed a Phase II NSF grant may next benefit from bridge funds offered by other government agencies, e.g. NIH; such transitions should be free of obstacles.

Moreover, as nanotechnology matures and concepts reach practical application, a greater emphasis on research in nanomanufacturing and commercial deployment is appropriate; nanomanufacturing refers to efficient and scalable methods for producing nanoscale materials and devices. Research in this area also includes development of advanced nanofabrication tools, new nanomaterials characterization methods with high throughput and differentiation, nanomaterials purification technologies, and nanomaterials standards. In addition, the NNI can help promote successful commercialization by supporting applied and translational research on the integration of nanoscale materials and devices into useful products—incorporating carbon nanotubes into composite materials or optimizing biohazard sensors for performance in battlefield environments, for example. Moreover, the establishment of standards is essential to growth of most new technologies, and nanotechnology is no exception. One approach to facilitating standards development would be to establish a "Particle Foundry" that produces standard particles of common nanomaterials of controlled size, shape, and composition for scientific researchers and industry.

Advances in all of these areas are necessary for nanotechnology to realize its enormous technological and societal impact. Nanomanufacturing and commercial deployment should also be a key component of a broader national mission in advanced manufacturing innovation that would allow the United States to level the playing field in competition with countries with labor cost or natural resources advantages. As part of this emphasis, the NNI should continue to establish new Signature Initiatives. One of these could be the development of the "Desktop Fab," that is, a system that has the ability to make prototype versions of nanostructures rapidly at the point-of-use, an effort that would require a large multi-million dollar facility today. Such a development could represent a manufacturing advance with impact analogous to that of desktop printing in personal computing. Other challenges could include setting goals such as creating low-cost solar cells or building lightweight ultra-efficient vehicles, to spur applied and translational research directed toward those applications.

During its second decade, the NNI should adopt an explicit goal to focus research in areas that by the end of the decade results in measurable job creation in the United States. Taxpayers deserve a return from the public research dollars invested in nanotechnology, and the NNI should account for the impact this research is having on the economic conditions of average Americans, and direct future research to areas that are likely to benefit American firms. The NNI should have some funding of its own that it can direct toward encouraging entrepreneurship in the nanotechnology field. The NNI could use such funding to help companies more successfully navigate the "valley of death" and to develop manufacturing capability in the United States for producing strategic nanotechnology products.

Recommendation 3-2: Job Creation

The Department of Commerce and the Small Business Administration should advise the NNI on how to ensure that its programs create new jobs in the United States, including coordinating with State efforts, and economic impact should be an explicit metric in the second decade of the NNI.

As noted earlier, the United States educates more of the world's talent in nanoscience and engineering than any other country, and then exports much of that talent. One solution would be to develop a program to provide U.S. Permanent Resident Cards for foreign individuals who receive an advanced degree in science or engineering at an accredited institution in the United States and for whom proof of permanent employment in that scientific or engineering discipline exists.

Recommendation 3-3: Workforce Retention

Congress and the Administration need to take steps to retain scientific and engineering talent trained in the United States by developing a program to provide U.S. Permanent Resident Cards for foreign individuals who receive an advanced degree in science or engineering at an accredited institution in the United States and for whom proof of permanent employment in that scientific or engineering discipline exists.

Innovative technologies cannot be developed on a series of $100,000, nine-month grants when the fully-burdened cost of supporting a single Ph.D. scientist in a research company is about $300,000 annually. Therefore, the NNAP believes that the NNI needs to make sustained and substantial investments in focused areas. Among existing government programs, the NIST Technology Innovation Program (TIP) is a good model; it provides for multi-year, multi-million-dollar investments to help companies developing new nanotechnologies cross the infamous "valley of death." VC-backed start ups should not be excluded from Federal Government grants to facilitate commercialization.

Recommendation 3-4: Moving Nanotechnology to Market

The DOE, DOD, NIST, NIH, NCI, FDA, and NIST should clarify the development pathway and increase their emphasis on transitioning nanotechnology to commercialization, including making sustained meaningful investments in focused areas to help accelerate technology transfer to the marketplace.

Case Studies

During the past decade, the nanotechnology R&D community has made an enormous number of discoveries with the potential for wide-ranging societal impacts. The majority of these developments remains at embryonic or proof-of-concept stages and have not yet begun a trajectory toward the marketplace. Among the great many significant discoveries that could become the basis of future commercial technologies are:

- **Graphene transistors**—The use of graphene (single layers of carbon atoms in a chicken wire geometry) as the semiconductor in transistors promises to improve performance and keep the electronics industry on the path of miniaturization, but researchers need to learn to control the material's properties before they can realize its potential. With strong support from the semiconductor industry, commercialization could come within the next decade.
- **Nanomotors**—These molecular machines, akin to a cell's enzymes, have the potential to revolutionize the way researchers control atoms and construct materials. However, investigators pursuing nanomotors are breaking into uncharted territory; valuable and practical implementations remain decades away.
- **Metamaterials**—These synthetic materials enable the manipulation of electromagnetic (EM) waves in new ways, offering the potential for significant advances in communication technologies and the control of light. Early simple applications may reach the market in 10 years.
- **Silicon nanowire thermoelectrics**—Silicon nanowires could significantly lower the cost of thermoelectric devices that convert heat directly into electricity, paving the way for broader adoption. Widespread waste-heat recovery would have a worldwide, immediate impact. Another 10 years of development is likely necessary before silicon nanowire thermoelectrics will be ready for the spotlight.

- **Plasmon-enhanced solar cells**—Properly designed metal nanoparticles can scatter incoming light, and when laid down as a layer can greatly increase efficiencies of solar cells. Practical demonstrations have been made and scalable processes for making the nanoparticles are available, opening a potential pathway to bringing plasmon-enhanced solar cells to the market in about five years.

Some nanotechnologies have matured beyond early stages of development and represent significant progress toward the goal of delivering commercially consequential technology that NNI has fostered directly and indirectly. The case studies that follow specifically focus on commercialization milestones since the last NNI review.

Advanced Batteries—The small size, light weight, and high-energy density of lithium ion batteries, first commercialized in the early 1990s, proved perfect for consumer electronics devices such as laptop computers and cell phones. However, these batteries were not suitable for large-scale energy applications. To meet the needs of large-scale applications, A123 Systems (Hopkinton, MA) developed its patented Nanophosphate™ technology, based on nanoscale lithium metal phosphate cathodes with compositionally and structurally engineered phase stability and lithium transport kinetics. A123's technology provides the necessary combination of high energy density, high power, safety, long life, environmental friendliness, and low cost to enable applications in transportation and the electric grid.

The company, founded in 2001 to commercialize technology developed at MIT with DOE funding, brought its first product to market in 2005, a cell developed to power a new line of premium, contractor-grade cordless power tools for Black and Decker's DeWalt product line. Today, the company has more than 2,000 employees and is at the forefront of creating a battery industry in the United States that will help change the way the Nation produces, stores, and uses energy. A123 has built on its core technology to develop advanced batteries and entire battery systems to help bring in a new era of sustainable transportation, including plug-in hybrids and battery electric vehicles for both passenger and commercial vehicles.

In addition, A123 is developing new energy storage solutions for the electric grid across the entire range of applications including generation, transmission, and distribution. These products will help create a power generation and delivery system that is more efficient and makes the most of existing power-generating assets. These products also will assist in the integration of renewable energy sources, such as wind and solar power, by smoothing their output and stabilizing the grid, thus allowing those technologies to achieve their full potential. Development of these nanotechnology-based products will reduce reliance on foreign oil, invigorate advanced manufacturing in America, and help meet the global imperative for greater energy efficiency.

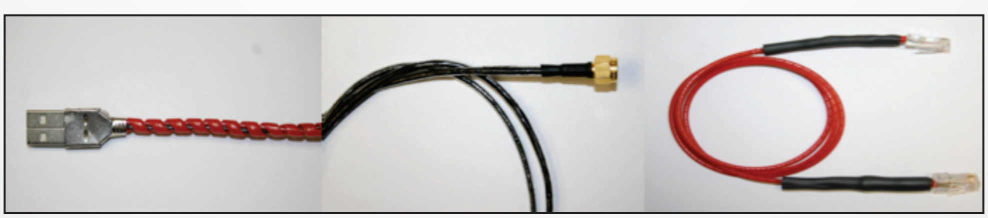
The company was started using an initial $100,000 SBIR grant from the DOE. Since then, A123 has raised $350 million in private capital from investors that include GE, and was awarded a $249 million DOE battery manufacturing grant in 2009. The company is expanding its lithium ion battery manufacturing facilities in the United States, beginning with facilities in Michigan that will stimulate the economy through the creation of high quality jobs in the short term, and play a key role in building a stable, self-sustainable and globally competitive U.S. battery industry in the long term. The company raised $428 million in an IPO in September of 2009 that was one of the largest of the year.

Lightweight Wiring and Body Armor—Today's military conducts complex missions against unpredictable threats. A key to mission success is the use of highly digitized, network-centric and space-based systems to provide command and control, reconnaissance, and communications for the warfighter and national command authority. Ironically, these state of the art systems are dependent upon 19th century technology—heavy copper wires and cables. One third of the weight of a satellite is found in wiring harnesses, and given that it costs up to $100,000 to lift one pound of mass into orbit, the use of copper comes with a significant weight penalty. Similarly, a civilian airliner such as the Boeing 787 has over 60 miles of copper wire, weighing many thousands of pounds and thus providing a serious drag on fuel economy.

A 21st century replacement for copper is at hand, thanks to NNI-associated activities. Nanocomp Technologies, Inc., (Concord, NH) has spent the last five years developing a process technology that grows ultra-long carbon nanotubes (CNTs) and simultaneously fabricates them using automated equipment into sheets and spun yarns. Working with Northrop Grumman's Aerospace Division and the Air Force, Nanocomp has developed a CNT-based electrical core conductor and cable shielding that can be used as a lightweight, robust substitute for shielded copper wiring. For the first time, CNT cables have achieved high fidelity USB 2 data transmission rates equal to that of off-the-shelf cables. In 2009, the company demonstrated that Category 5 CNT materials are reducing the weight of cable harnesses by 33–70 percent, with the potential of eliminating hundreds of pounds per spacecraft and thousands of pounds per aircraft. Weight reduction of this scale could produce fuel savings totaling tens of millions of gallons over the lifecycle of a commercial jetliner and reduce the environmental impact of commercial air travel by reducing carbon dioxide emissions at a scale of hundreds of millions of pounds.

Additionally, work funded by the Air Force and Lockheed Martin has shown that Nanocomp's nanotube sheets significantly improve the resistance of military aircraft and satellites to electromagnetic interference and electromagnetic pulses. NASA's upcoming Juno space mission to Jupiter will, for the first time, use nanotube sheets to protect the spacecraft from electrostatic discharge. Civilian aircraft will also benefit as these same CNT materials can enhance the protection of avionics systems. Ultimately CNT materials developed for military shielding will find use in consumer electronics, such as smart-phones, that also require high performance EMI shielding to assure their operation.

Since 2005, the Army's Natick Soldier Center has supported work to use the company's CNT materials to help decrease the weight and improve protection of body armor. In 2009, the company's nanotube composites successfully defeated bullets – a promising milestone for lightweight body armor. CNT based lightweight armor will also find broad use in ground vehicles, helicopters, and fixed wing aircraft. The armor program has also yielded strong, lightweight composite materials for military satellites and aircraft with the potential to address energy savings in civilian markets such as windmill blades and automotive products.



Fully Functional CNT cables from left: USB, Coaxial, and Cat 5 Internet cables.

Antimicrobial Technology—The intense focus on nanotechnology created by the NNI over its first decade has encouraged many established companies to start internal nanotechnology research and development efforts. For example, Baxter International (Deerfield, IL) has developed and commercialized the Vitalshield® technology that uses silver nanoparticles to reduce catheter-related blood stream infections (CR-BSIs) and serves as an example of the leverage that the NNI provides in product and job creation even when direct funding is not provided.

It is estimated that more than 400,000 cases of CR-BSI occur each year in the United States. CR-BSIs increase average duration of hospital stay by 23 days and raise mortality by 18 percent. The increase in direct costs to hospitals has been estimated to range from $13.8 billion and $22 billion annually. While migration of skin organisms at the catheter insertion site is a common route of infection, contamination of the catheter hub contributes substantially to intraluminal colonization of long-term catheters.

In Vitalshield®, the silver nanoparticles create a permanent, nonflaking coating on catheters that continually generates a thin layer of antimicrobial silver ions. Each nanoparticle in the structure develops a surface layer of silver oxide, which serves as a source of ionic silver upon contact with moisture. This oxide layer releases ionic silver into the surrounding fluid space and re-develops as a new layer of elemental (metallic) silver is exposed. This process continues with ongoing exposure to moisture providing a "reservoir" of ionic silver that is durable and persistent. Data show that the silver nanoparticles in Vitalshield® elute more than three times the available silver ions over a 96-hour period than zirconium phosphate embedded silver technology or in silicone elastomer.

IV. Nanotechnology and Environment, Health, and Safety Issues

Chapter Summary

By creating jobs, stimulating economic growth, and providing solutions to some of the toughest challenges facing humankind, nanotechnology has great potential to change the world for the better. Yet realizing this potential may be thwarted if the safety of new materials and products arising from nanotechnology is not addressed up front. In the absence of sound science on the safe use of nanomaterials and of technologies and products containing them, the chances of unintentionally harming people and the environment increases. At the same time, uncertainty and speculation about potential risks threaten to undermine consumer and business confidence. The proactive approach to addressing potential environment, health, and safety impacts of nanotechnology taken by NNI is commendable. Over the past two years, the NNI has released a cross-agency nanotechnology EHS research strategy, instigated multi-stakeholder workshops on nanotechnology EHS issues, and seen the Federal nanotechnology EHS research budget increase from $67.9 million in 2008 to a requested $116.9 million in 2011. Individual agencies have also played an active role in international efforts to develop nanotechnology responsibly.

Even so, potential EHS-related barriers still stand in the way of effective, sustainable, and responsible commercialization of nanotechnology. As the NNI continues to work toward "a future in which the ability to understand and control matter at the nanoscale leads to a revolution in technology and industry that benefits society," the NNAP recommends that member agencies increase coordinated efforts to overcome these barriers. Specifically, the NSET Subcommittee's interagency working group on Nanotechnology, Environmental, and Health Implications should develop clear principles to support the identification of plausible risks associated with the products of nanotechnology. The NSET Subcommittee's NEHI working group should also further develop and implement a cross-agency strategic plan that links EHS research activities with knowledge gaps and decision-making needs within government and industry. The NNAP also recommends that NSET Subcommittee implement organizational changes that support consequential cross-agency action on addressing nanotechnology EHS issues. In particular, the NNCO should specify an individual who would lead interagency coordination of efforts in the area of EHS. Finally, the NSET Subcommittee's NEHI working group should develop publicly-available information resources on cross-cutting nanotechnology EHS issues that are relevant to businesses, health and safety professionals, researchers and consumers.

Manufacturing, known in some sectors as fabrication, is a significant wealth-producing component of the American economy, and because manufacturing may pose a number of risks, manufacturing activities are governed by Federal labor laws and environmental laws. Whether manufactured nanomaterials pose unique risks is an important question. As nanotechnology has developed over the past decade,

those investing in, developing, using, or regulating products and processes have faced a significant challenge: how to ensure safe and responsible use where potential risks are uncertain. In recent years, media coverage has highlighted uncertainties over potential nanotechnology-related risks; experts have called into question the ability of governments and industry to ensure the safety of nanotechnology-based products; scientists have identified potential risks associated with a number of nanomaterials; and Congress has emphasized the need for the NNI to support the responsible development of nanotechnology. To some, the result has been an emphasis on EHS issues that threaten to raise unsubstantiated concerns, undermine consumer and investor confidence, and create regulatory barriers to innovation. These are valid concerns. And yet, rather than calling into question the relevance of EHS research, they emphasize the dangers of *not* addressing environment, health, and safety issues upfront.

Responsible and sustainable development depends on a commitment to develop and use products that meet human and societal needs, while making every reasonable effort to anticipate and mitigate adverse effects and unintended consequences. In the context of nanotechnology, responsible and sustainable development relies on science-informed and socially-responsive approaches to identifying, assessing, and managing risks. Research to date suggests that some products of nanotechnology have the potential to present new or unusual risks to human health and the environment. For instance, nanoscale particles may penetrate to places in the body that are inaccessible to larger particles; radical changes in behavior at the nanoscale may render harmful materials considered to be safe in larger-scale and more conventional forms.

In general, nanomaterials that have been shown to pose risk fall in two categories. They are either derived from bulk materials that are known to pose EHS risk (e.g. heavy metals), or they are nanomaterials made from bulk materials that are generally considered nontoxic but, when miniaturized and aerosolized, exhibit increased risk.

In the absence of more detailed scientific evidence—and effective assessment and communication of the evidence that does exist—the distinction between plausible and implausible risks remains unclear. The resulting uncertainty threatens to undermine confidence and trust amongst investors, businesses, and consumers, and could jeopardize the success of nanotechnology. This is not a hypothetical threat. Consumer and advocacy groups already have raised concerns over the use of engineered nanomaterials in products as diverse as clothing, fuel additives, and sunscreens. Businesses have been hampered by regulatory uncertainty. A number of industries have shied away from nanotechnology for fear of consumer rejection in the face of speculative concerns.

Against this backdrop, it is no surprise that the potential environment, health, and safety impacts of nanotechnology have been a central focus of the NNI for the best part of the past 10 years.

Progress on Addressing the 2008 NNAP Review

In proactively addressing nanotechnology EHS issues, the collective efforts of the NNI member agencies have broken new ground. A commitment to the responsible development of nanotechnology is evident both within the NNCO and the NNI member agencies. Significant progress has been made in funding relevant research since the inception of the NNI and in the two years since the previous NNAP review,[20] as

20. www.nano.gov/PCAST_NNAP_NNI_Assessment_2008.pdf

shown in Figure 4-1. Over the past two years, for example, NSF and EPA have jointly funded two Centers on the Environmental Impacts of Nanotechnology; EPA has collaborated with the British Environment Agency to fund nanotechnology EHS research; and the National Institute for Occupational Health and Safety (NIOSH) has increased intramural research efforts addressing potential health impacts from engineered nanomaterials in the workplace.[21] In addition, individual agencies are beginning to develop responsive internal strategies to specific nanotechnology EHS challenges. The number of publications on nano-related EHS issues is rising (see Figure 4-2), and the NNI EHS strategy[22] continues to mature with a program of ongoing, multi-stakeholder workshops feeding into its next iteration.

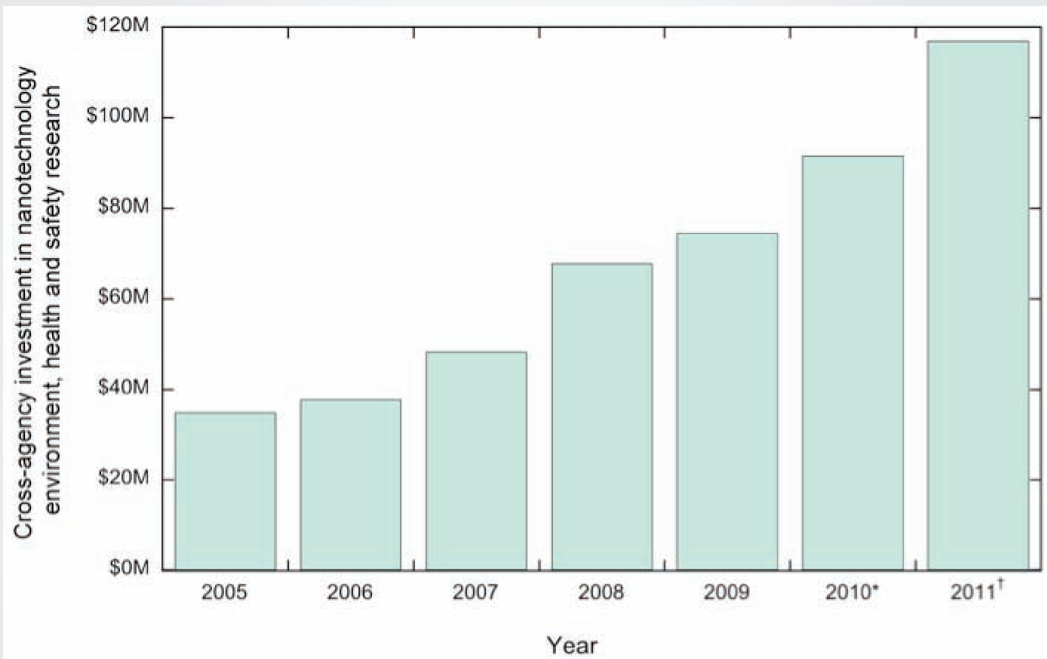


Figure 4-1. Cross-agency investment in nanotechnology EHS research, 2005–2011.

*Estimated. †Proposed.

Source: NNI supplements to the President's budget, 2007–2011.

Amidst all of this progress though, a question remains: Is enough being done to identify and mitigate potential risks and reduce EHS-related barriers to effective, sustainable, and responsible commercialization of nanotechnology-based products?

In 2008, the NNAP acknowledged the NNI's role in addressing nanotechnology EHS issues and supported the soundness of the NNI's approach to addressing potential risks arising from nanotechnology. Through 10 recommendations in its 2008 report (restated in bold below), NNAP pointed the way to further strengthening the NNI's activities to ensure the responsible development of nanotechnology. The NNAP

21. www.nano.gov/NNI_2011_budget_supplement.pdf
22. www.nano.gov/NNI_EHS_Research_Strategy.pdf

believes that in the two years since then, the NNI has made progress in addressing these recommendations, many of which remain relevant in 2010. In this rapidly developing field, a number of new priorities also have emerged that will shape the future perspectives and activities of the NNI. In what follows, the NNAP focuses on the progress the NNI has made regarding NNAP's 2008 recommendations and consider how the NNI might continue to support the emergence of responsible nanotechnology in the future.

1. ***Coordinate nanotechnology EHS strategy with industry and international stakeholders.*** Over the past two years, the agencies comprising the NNI have made substantial progress in coordinating the nanotechnology EHS strategy with industry and international stakeholders. Much of this progress has been led by individual agencies. The EPA, FDA, NIOSH, and the National Institute of Environmental Health Sciences (NIEHS), for example, have increased their level of interaction with industry and other stakeholders. Moreover, U.S. representatives continue to play key roles in nanotechnology EHS initiatives within the OECD, the International Organization for Standardization (ISO), and other international organizations and initiatives. Within the NNI, a series of workshops have been held that enable broader stakeholder input to developing and implementing a strategy for EHS research in the Federal nanotechnology portfolio. Although the NNAP feels that these workshops have occurred rather late in the process and do not fully address the degree of coordination required with industry and other stakeholders, they are an important and positive step forward. Nevertheless, there remains a need for greater coordination with industry and with other stakeholders that leverages nongovernment expertise and initiatives while minimizing unnecessary duplication of effort. Initiatives supporting further national and global partnerships between government, industry, and academia in addressing common nanotechnology EHS challenges are encouraged. Specifically, the NNAP suggests that channels of communication between relevant State and Federal agencies be established, which support information sharing on emerging nanotechnology EHS challenges and their potential solutions. Regarding industry, the sharing of nonproprietary information between industry and government remains difficult under existing frameworks and approaches to overcoming this barrier to progress should be investigated.

2. ***Do not segregate implications research and applications research. In many instances, nanotechnology EHS research cannot be separated from the particular application(s) research and from the context for which a specific nanomaterial is intended.*** In contrast with the previous NNAP review, the members of the current NNAP believe that EHS research must be closely linked to applications research but that too great an emphasis on integration has the potential to jeopardize both applications and EHS research. Overly intimate integration of these two categories of research can lead to a muddling of research priorities. At the same time, there is a danger of resource-intensive EHS research compromising exploratory and applications-based research programs. To avoid those outcomes, the NNAP encourages a collaborative approach among communities involved in exploratory research, applications research, and EHS research that allows risk-researchers the freedom to identify and address issues from the perspective of protecting human health and the environment. To help achieve this, the NNI should encourage greater communication between communities developing nanotechnology-based applications and those addressing potential risks, and should foster a culture of mutually beneficial

interdisciplinary collaboration between these communities. Importantly, the NNAP emphasizes the need to establish EHS research projects and programs that are led by researchers with expertise in identifying and addressing potential risks.

3. ***Continue developing joint programs among NNI agencies that leverage expertise and resources to conduct nanotechnology EHS research and to support agency missions.*** Member agencies of the NNI continue to work together and to leverage internal resources in addressing nanotechnology EHS. Over the past two years, EPA and NSF have jointly funded two major centers addressing environmental implications of nanotechnology. These investments will total some $38 million over the next five years. NIEHS, NIOSH, and FDA continue to collaborate on supporting research into the safety of nanomaterials through the National Toxicology Program. NIOSH and EPA have also worked together on developing workplace safety requirements for nanomaterials under the Toxic Substances Control Act. The NNAP encourages NNI member agencies to continue developing joint programs. In particular, the NNAP encourages stronger collaborations between oversight-focused agencies, which lack funding resources for research, and agencies with substantial research resources. Specifically, the NNAP encourages the development of risk-relevant research programs supported by research agencies such as NSF and NIH that are responsive to the perspectives and decision-making needs of regulatory agencies such as FDA, EPA, CPSC, and the Occupational Safety and Health Administration (OSHA).

4. ***Support wide distribution and availability of new nonproprietary information about the properties of nanomaterials.*** Following through on this recommendation remains important within the United States if nanotechnology-based products are to be developed responsibly and successfully. The NNAP is concerned that the recommendation, as it was stated in 2008, misses an important requirement: it does not address directly the challenge of ensuring open access to health and safety data while safeguarding confidential business information (CBI). Over the past two years, there has been only modest progress in collecting and disseminating non-proprietary information within the Federal Government. The recently ended EPA Nanoscale Materials Stewardship Program,[23] for instance, received a limited response from industry. The NNAP strongly encourages the NNI to rise to the challenge of developing mechanisms that allow broad access to EHS-relevant data by state and local regulatory and enforcement agencies, as well as the public, while respecting legitimate CBI claims. The NNAP also encourages the NNI to develop more effective mechanisms for rapidly disseminating information generated within the Federal Government and by State agencies. At the time of writing this NNAP review, for example, the results of an NNI workshop on exposure assessment held on February 24–25, 2009, have yet to be published.[24] Shortening the period between information gathering and information dissemination from years to months will support coordinated and strategic action on identifying and addressing nanotechnology EHS issues in a timely manner.

5. ***Assess the Federal nanotechnology EHS portfolio and update gap analysis against research priorities triennially.*** In February 2010, the NRC launched a four-year study, funded by the EPA, which will contribute significantly to addressing this recommendation by the prior NNAP. The statement of task for the study requires that the panel, "will create a conceptual framework for

23. www.epa.gov/oppt/nano/stewardship.html
24. www.nano.gov/html/meetings/exposure/index.html

environmental, health and safety-related research; implement this research plan; and subsequently evaluate research progress over a three year period of time." The first report from the project is scheduled to be completed by midyear 2011.

6. ***Leverage opportunities to bootstrap identified gap areas and to encourage increased investments elsewhere through collaboration with industry and other countries; encourage broad and ongoing agency participation in such efforts.*** Agencies within the NNI continue to leverage opportunities to collaborate with industry and other countries. Collaborations between Federal agencies, industry, and the OECD, ISO, and the United Kingdom Environment Agency continue to leverage international activities and investments. The NNAP strongly encourages that these activities be continued and expanded.

7. ***Encourage supported researchers to report on the development of analytical methodologies used in their research so that a series of best practices can evolve for risk assessment and characterization.*** The lack of good practices for materials characterization and approaches to risk analysis remains a critical challenge to conducting robust EHS-related studies and ensuring that risk-focused research is suitable for informing risk-based decisions. Over the past two years, Federal employees have been associated with initiatives addressing good practices in nanotechnology EHS research, including the MinChar Initiative,[25] the International Alliance for NanoEHS Harmonization,[26] and activities within the ISO and the OECD Working Party on Manufactured Nanomaterials. The NSET Subcommittee, however, has not taken a clear leadership role in supporting federally funded researchers in contributing to risk assessment and the development of good practices in materials characterization. The NNAP strongly recommends that the NSET Subcommittee take leadership roles in this area.

8. ***Promote broad and practical use of EHS findings in defining responsible use of nanotechnology in research, manufacturing, and commercial application.*** Although the NNAP feels that agencies within the NNI have made progress on this recommendation over the past two years, there is room for significantly more progress. In particular, where EHS issues cut across agencies, the NNI has a unique opportunity to act as a central point of contact for information and guidance, an opportunity that it has not yet taken. One approach to promoting broad and practical use of EHS findings would be to develop general principles for utilizing such findings. These principles would ensure alignment and consistency among the agencies with various oversight responsibilities as they propose actions based upon the EHS findings. The NNAP recommends that the NNI develop a set of such principles.

9. ***Increase exposure assessment funding***. Exposure assessment research has been receiving more attention within the NNI over the past two years. NIOSH is collaborating with the CPSC on studying the potential of human exposure from use of selected spray applications utilizing nanomaterials. In February 2009, the NNI held a workshop on human and environmental exposure assessment that led to input from a range of stakeholders. In addition, the FY 2011 budget request for nanotechnology EHS research will provide increased funding for exposure assessment research. Nevertheless, a survey of the International Council on Nanotechnology

25. www.characterizationmatters.org
26. www.nanoehsalliance.org

(ICON) nanoEHS Virtual Journal[27] indicates that only 13 percent of the collected papers (spanning 2000–2009) directly address exposure, as shown in Figure 4-2. The NNAP strongly recommends that funding for research on nanomaterial exposure issues be increased further, and that these increases are sustained over a number of years to ensure the development of robust and relevant exposure assessment tools.

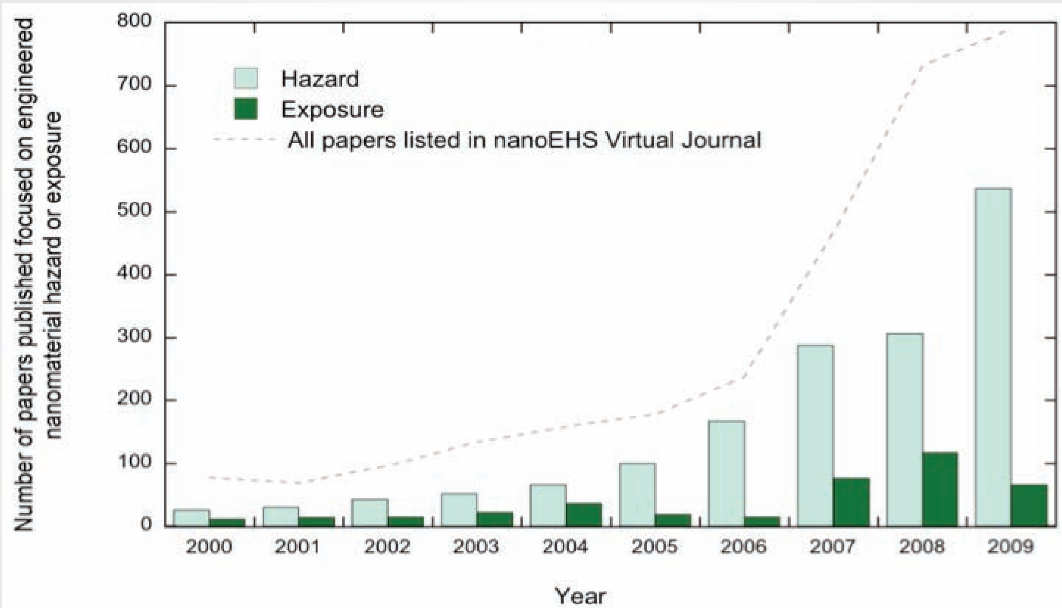


Figure 4-2. Number of published papers listed in the ICON nanoEHS Virtual Journal that focus on engineered nanomaterial hazard and exposure, compared to the overall number of papers related to nanotechnology EHS. Listed papers represent global publication output.

10. ***Maintain and strengthen agency support and coordination efforts through the NSET Subcommittee and its NEHI working group***. In early 2010, the director of NIOSH was established as co-chair of the NSET Subcommittee's NEHI working group. This is a welcome move, demonstrating senior-level agency support for the NSET Subcommittee's NEHI working group and the NSET Subcommittee. The NNAP encourages the NNI to follow this lead and work toward engaging other agencies at a senior level, ensuring that the NSET Subcommittee's NEHI working group and the NSET Subcommittee are in a position to contribute to high-level decision making within member agencies.

27. www.icon.rice.edu/virtualjournal.cfm

Hurdles to Future Progress in Addressing Nanotechnology EHS Issues

Looking to the future, the NNAP has identified six potential hurdles that NNI leadership faces as it strives to make further progress on ensuring the responsible development of nanotechnology:

1. ***Leadership and accountability***— Clear leadership and accountability continues to be important in identifying and addressing crosscutting issues and ensuring a sound risk-based approach to R&D and its subsequent use. Within the current NNI structure, the NNAP has not been able to identify an accountable individual who has direct experience in risk research, understands what it takes to translate that research into decision making, and is in a position to engage with member agencies at a senior level. Similarly, it is not clear who, or which organization, is accountable for cross-agency actions on ensuring the development of responsible nanotechnology, including implementing the recommendations in this review. Leadership and accountability on nanotechnology EHS is essential to raising confidence in the NNI within business and consumer communities and to enabling the United States to take a leadership role on the international stage.

2. ***Stakeholder engagement***—The NNI needs to more actively engage stakeholders on nanotechnology EHS issues if it is to address these issues effectively. Engagement so far has involved participation in nongovernment and international initiatives, public hearings, and, more recently, in a series of EHS-related workshops. These efforts need to be expanded substantially if Federal research strategies are to reflect stakeholder needs and the current state of the art with nanotechnology EHS.

3. ***Connecting research to decision making***— To encourage the responsible and successful development and introduction of nanotechnology-based products, stakeholders need to work harder to bridge the gap between nanotechnology EHS R&D and decision making. The NNAP suggests that applied EHS research should be driven, at least in part, by the need to make informed decisions on risk assessment and management, and on materials and product oversight. The current structure of the NNI has not facilitated effective linkage of risk research and decision making, and this disconnect has resulted in actions and strategies that do not fully address policy needs. At the moment, in lieu of NNI coordination, individual agencies are unilaterally orchestrating effective connections between research and decision making. EPA and NIOSH, for example, have targeted their nano-related research strategies to fill knowledge gaps that are impeding decision making. Similar efforts are needed at an interagency level to ensure that cross-agency issues, such as dealing with uncertainty, risk assessment, and evidence-based decision making, are addressed appropriately.

4. ***Framing the EHS risk issue***—In framing nanotechnology EHS research within the context of an initiative focused primarily on promoting exploratory research and innovation, some science-based questions appropriate to EHS impacts are being missed. The NNI definition of nanotechnology has limited relevance to addressing new risks. Yet regulators and risk assessors are being pushed to address materials and products that fit inside this definition of nanotechnology, rather than being encouraged to develop a science-based approach to risks that is not bound by arbitrary (from a risk perspective) definitions. As a result, the focus is on size as

a determinant of risk, rather than emerging risks *per se*. Continuing to frame EHS issues within the current terms of the NNI runs the double danger of raising illegitimate concerns that have no evidentiary backing, while obscuring real ones.

5. ***Research strategy***—The responsible development of nanotechnology is dependent on a clear multi-stakeholder research strategy that ensures that regulators, businesses, consumers, and others have the information and tools they need to develop and use new products safely. While the NNI has been active in developing a Federal strategy, the effort has some way to go before it fully addresses the needs of stakeholders. In 2009, an independent review panel convened by the NRC concluded that the NNI, "does not have the essential elements of a research strategy" for addressing nanotechnology-related EHS research.[28] The NNAP strongly recommends that the NNI build on this NRC review as it further develops an effective cross-agency EHS research strategy.

6. ***Targeted funding—***In the past, discussions over how well the Federal Government's nanotechnology effort is doing in the EHS realm have focused, to a great extent, on how much money the government is spending in this area. This focus has led to apparent discrepancies between NNI-identified investment in EHS-related research and independent assessments. In 2008, the GAO concluded that only 80 percent of research projects identified by the NNI as being relevant to EHS actually were relevant in this way.[29] Similarly, the 2009 National Research Council review of the NNI EHS research strategy concluded that in regard to nanotechnology EHS research, "the relevance of FY 2006 research projects to the research needs is generally overstated."

The NNAP acknowledges the importance of adequate funding and appropriate accounting of nanotechnology EHS research. That said, the NNAP suggests that appropriate and targeted funding for strategic nanotechnology EHS research is more important than absolute dollar amounts. To ensure that emerging EHS issues are addressed effectively and in a way that yields useful information for regulators and policymakers, the NNI needs to help the scientific community establish a substantial core of exploratory research into biological and environmental interactions with nanomaterials. In addition, the Federal Government needs to ensure sufficient funds are available to mission-driven agencies to address specific issues that are arising.

A number of reports—including the NNI's 2008 EHS research strategy[30]—have identified specific knowledge gaps that need to be filled in order to underpin effective risk assessment and management. Although the NNI has no budget or allocation authority, it is critical that mechanisms are identified and developed to ensure agencies such as NIOSH, EPA, NIEHS, and FDA have access to sufficient funding to ensure these knowledge gaps are filled. Recent budget requests for nanotechnology EHS research indicate that moves are being made to ensure a more appropriate targeting of research funding. Within a record request for nanotechnology EHS funding of $116.9 million for FY 2011, three times the equivalent budget request of five years ago, agencies such as NIOSH, EPA, FDA, and CPSC are in line to receive *substantial funding increases for nanotechnology EHS research. Significantly, this will be the first time that FDA and CPSC will have had a specific allocation of funds to cover nanotechnology, a welcome move and one that the NNAP hopes is sustained over a number of years.

28. www.nap.edu/catalog.php?record_id=12559
29. www.gao.gov/products/GAO-08-709T
30. www.nano.gov/NNI_EHS_Research_Strategy.pdf

Recommendations

Recommendation 4-1: Risk Identification

The NSET Subcommittee's NEHI working group should develop clear principles to support the identification of plausible risks associated with the products of nanotechnology.

These principles should be high-level and should underpin effective problem formulation in crafting approaches to addressing emergent nanotechnology-related risks, which are defined here as risks that arise in unanticipated and poorly understood ways by virtue of the size and shape of the materials. Such risks thus transcend established approaches to risk assessment and management.

These principles should make it possible to differentiate those products of nanotechnology that are unlikely to present significant emergent risks from those that are more likely to do so. These principles should clarify that plausible risks depend both on hazard *and* a real likelihood of exposure, and support strategic action toward the goal of increasing certainty and predictability when addressing the safety of nanotechnology-related products. The principles should be made available to, and be suitable for use by, nanotechnology developers, users, and regulators.

Recommendation 4-2: Strategic Planning

The NSET Subcommittee's NEHI working group should further develop and implement a cross-agency strategic plan that links EHS research activities with knowledge gaps and decision-making needs within government and industry.

The strategic plan should respond to knowledge gaps identified in previous assessments of research needs, including the 2008 NNI EHS research strategy and the 2009 NRC review of the strategy.[31] In particular, the plan should ensure an appropriate balance between research addressing the release of engineered nanomaterials, human exposure to such releases, and the biological impacts of these materials following exposure. In addition, the strategic plan should support exploratory research that leads to new knowledge while ensuring a robust program of targeted research that addresses identified issues in a timely manner.

Mechanisms for closer integration and partnering between agencies that fund exploratory and applied research should be explored. The NNAP also encourages the formation and support by the NNI of investigator networks to facilitate the development of harmonized research methodologies. The strategic plan should be coordinated with the broader nanotechnology EHS research strategy currently being developed by the NRC. In the near term, the development and implementation of NNI's revised plan

should be expedited and should not await the release of the NRC's strategy. The plan should also be reviewed on a regular basis—both internally and by nongovernment experts—and be updated when necessary.

31. www.nap.edu/catalog.php?record_id=12559

Recommendation 4-3: Organizational Changes

The NSET Subcommittee and OSTP should foster administrative changes and communications mechanisms that will enable the NNI to better embrace the EHS issues associated with nanotechnology research, development, and commercialization.

- The NSET Subcommittee co-chairs should assign an individual to NNCO to oversee interagency efforts that address nanotechnology EHS.
- OSTP and the NSET Subcommittee should expand the charter of the NEHI working group to enable the group to address cross-agency nanotechnology-related policy issues more broadly.
- The NSET Subcommittee should explore mechanisms that enable the NEHI working group to more effectively receive input and advice from nongovernment experts in the field of emergent risks.

The EHS-related point person within NNCO should constitute a liaison for stakeholders within and outside government on nanotechnology EHS issues, be able to interact with agencies at a senior level, and have a keen understanding of and experience with risk research and its relevance to decision making. This EHS leader within the NNI should be accountable for cross-agency actions toward the responsible development of nanotechnology-based products and processes, including development and implementation of the nanotechnology EHS strategic plan.

In this respect, the NSET Subcommittee's NEHI working group should not be bound by the NNI definition of nanotechnology. Instead, the NSET Subcommittee's NEHI working group should be encouraged to develop a risk-focused scope that encompasses nanoscale materials and products that potentially lead to new risks and/or challenge current approaches to risk assessment, management, and oversight.

In particular, the value of establishing a Federal Advisory Committee that would enable experts and stakeholders in the field of nanotechnology EHS to provide the NNI with expert advice, input, and information on a regular basis should be evaluated. The NNAP feels that such a committee could strengthen considerably the robustness and relevance of Federal actions in addressing nanotechnology EHS, while reducing the likelihood that cross-agency activities will fail to match up with stakeholder expectations.

Recommendation 4-4: Information Resources

The NSET Subcommittee's NEHI working group should develop information resources on crosscutting nanotechnology EHS issues that are relevant to businesses, health and safety professionals, researchers, and consumers.

These information resources could include, but should not be limited to, the use and safety of nanomaterials in consumer products; "safety by design" approaches to developing these materials and products; risk assessment and risk management of nanotechnology-based products; and life-cycle approaches to responsible nanomaterial use.

Ten years ago, the United States blazed a new trail for national technology policy in its formation of, and investment in, the NNI. Its vision of new technologies and industries made possible by controlling matter on the nanoscale is fast becoming a reality. However, innovation alone is not enough for catalyzing a new economy in the 21st century. It also requires an early and honest evaluation of the possibilities that these same innovations could inadvertently cause harm. The public's and policymakers' perceptions of such risks will shape the commercialization path of emerging nanotechnology-based industries perhaps even more than the brilliance of the innovations. The NNI should leverage its international leadership and proven track record in research coordination in this area. Its ability to promote EHS research, coordinate research activities nationally and internationally, and speak to all nanotechnology stakeholders is singular among the agencies and is exactly what is required for this young industry.

V. Nanotechnology Beyond 2010

Chapter Summary

The NNI was established 10 years ago with an optimistic and sweeping vision in which virtually every category of technology would, in time, be transformed as scientists and engineers became ever more adept at engaging and controlling matter on the nanoscale. In the years since, researchers have taken many steps toward realizing that vision in a range of areas that include materials, information technology, health care, energy, and national security. Over the next 10 years, various nanotechnologies that have been under development are likely to find their places in society and new ones will emerge from the core of fundamental research that underlies nanoscience and nanoengineering. The NNI's role in the coming years will need to coevolve with the maturing nanotechnology era.

In its January 2000 press release announcing the NNI, the White House included a visionary list of potential long-term outcomes of the initiative:

- Shrinking the entire contents of the Library of Congress in a device the size of a sugar cube through the expansion of mass storage electronics to multi-terabit memory capacity that will increase the memory storage per unit surface a thousand fold.
- Making materials and products from the bottom up, that is, by building them up from atoms and molecules. Bottom-up manufacturing should require less material and pollute less.
- Developing materials that are 10 times stronger than steel, but a fraction of the weight for making all kinds of land, sea, air, and space vehicles lighter and more fuel efficient.
- Improving the computer speed and efficiency of minuscule transistors and memory chips by factors of millions.
- Using gene and drug delivery to detect cancerous cells by nanoengineered magnetic resonance imaging (MRI) contrast agents or target organs in the human body.
- Removing the finest contaminants from water and air to promote a cleaner environment and potable water.
- Doubling the energy efficiency of solar cells.

This is a list that reflects perceived societal needs and objectives at the turn of the millennium. Looking back at the last decade of the NNI and its accomplishments—both anticipated and unexpected—the NNAP believes it can gauge its success and suggest a vision of the future.

Extending the Capabilities of Information Technology

The January 2000 press release mentioned an audacious goal of "shrinking the entire contents of the Library of Congress in a device the size of a sugar cube." The writer apparently envisioned some leapfrog technology that goes far beyond the hard disk drive. In the past decade, that old technology, based on reading and writing digital information on a spinning magnetic disk, has continued to improve, but today there is more excitement about reading and writing information in devices that have no mechanical moving parts. We now take for granted that countless books, songs, pictures, and movies can be stored on silicon chips small enough to fit inside cameras, cell phones, music players, and many other consumer products.

Each memory cell on these chips is a silicon field effect transistor (FET) of a particular design that has been around for many decades. This means that today's rapid progress in information storage is the result of industrial investment in R&D that has been driving incremental improvements in the miniaturization of an old solid-state memory technology. Experts agree that this technology is approaching its physical limits, but new and different solid-state memory technologies are already being tested in the market. Phase-change memory cells and magnetic random access memory cells are built from materials other than silicon and involve operating principles different from those of the transistor. Thus, further progress in solid state memory is assured, but only because the seeds of that progress had been sown by way of fundamental research done many decades ago and because the means of commercialization as well as end markets for these products have long been in place. The NNI has not yet had time to make a significant impact on these developments in memory technology, but it is poised to carry the baton forward toward the ultimate limits of information storage.

Perhaps even more important for the future of information technology, the NNI is helping to focus researchers on a more difficult problem: the search for a new device for *processing* information, as opposed to storing it. In contrast to the emerging memory devices, there is no new device waiting in the wings to replace the FET for digital logic. Yet economic constraints on power dissipation and handling of heat have halted improvements in computing speed for the last five years. The individual devices on chips continue to get smaller and cheaper, but the chips generate more heat. The transistors are unable to run faster because it is technically too difficult to cool them in affordable ways. That is why manufacturers now tout the number of cores (microprocessors) they can integrate on a single silicon chip, rather than the ever-increasing processor clock speeds that they used to rely on for marketing. Unless the FET is re-invented or replaced by some revolutionary "new switch" for digital logic in the next few years, the information technology industry will lose much of its dynamism.

To stave off such a loss, leading microelectronics manufacturers in the United States have been pooling their financial resources, through a consortium known as the Semiconductor Research Corporation, to promote forward-looking university research that could provide the foundation for future generations of electronics technologies. As that tradition of collaboration moves further into the nanotechnology era, these companies embarked several years ago on a new research thrust, called the Nanoelectronics Research Initiative (NRI)[32]. In building this initiative, they built on research infrastructures and collaborative frameworks forged under follow the NNI.

32. nri.src.org/member/about/default.asp

Today, the NRI is a superb example of industry-university cooperative research, involving more than 30 top universities in the United States. Many of the research projects are organized around four multi-university centers that are funded partly by the State governments of California, New York, Texas, and Indiana. Other funding goes to various NSF NSECs. NSF and NIST each solicit additional research proposals and support the top proposals through the NNI. Individual research projects focus on new device concepts, particularly those that promise to break the power dissipation bottleneck that is limiting computing speed.

It all looks straightforward in hindsight: companies pooling resources to encourage pre-competitive university research in the hope of revitalizing their industry, state governments promoting regional development of R&D talent and infrastructure, and Federal funding agencies investing in forward-looking research that is in the national interest. But NNI played a catalyzing role. It would have been far more difficult to get this going without the NNI, which highlighted the long-term potential of nanotechnology investment for State governments and helped to steer some NSF funding toward NSECs and other relevant university-based research.

By pooling their resources, some forward-looking companies have been able to leverage some of this research capability in directions critical to the future of information technology. The impact of their investment has been magnified, and the odds of a big return on that investment in the coming decades have been substantially increased. Exploration and development of new devices for information technology will remain a grand challenge in the coming decade and the NNI is in a position to play important orchestrating roles.

Health Care in the 21st Century

That visionary White House press release a decade ago pointed to the use of designed nanostructures for diagnosis and treatments of cancer. "Within three years, researchers and program managers at the National Cancer Institute were contemplating "game changing" ways of taking on cancer. Based on promising research results going back to the late 1990s, these NCI personnel began to create a nanomedicine program with a focus on cancer. With an eye on going beyond basic research toward nanomedicine technologies, the NCI recruited scientists with physical and chemical backgrounds along with clinicians to discuss how nanotechnology might help physicians detect and quash cancer.

Those involved in this organizational development credit the NNI with playing an important role in convincing NCI to launch its first large-scale program in nanotechnology, the NCI Alliance for Nanotechnology in Cancer.[33] The mere existence of the NNI demonstrated to the decision makers at NCI that the highest level of government was supporting a national, multi-agency effort in nanotechnology. The NNI's presence made it clear that there was Presidential support for a program in nanotechnology in the health sector and it showed that the NCI would not be out on its own with a nanotechnology program.

Proving that point, NNI leadership assisted the NCI Nanotechnology Alliance in creating multi-agency programs and facilities, including the Nanotechnology Characterization Laboratory (NCL)[34] with NIST,

33. nano.cancer.gov/
34. ncl.cancer.gov/

FDA, and other partners. On its Web site, the NCL describes its role as "a national resource and knowledge base for all cancer researchers to facilitate the regulatory review of nanotechnologies intended for cancer therapies and diagnostics."

At the moment, advances in nanomedicine are unfolding along several lines, among them analysis of medical samples, imaging, and therapeutics. The ability to measure multiple types of proteins, DNA, RNA, and other telling molecules, in ever tinier samples of blood and other tissues and in ever shorter times, is leading to medically-relevant data sets of unprecedented richness and value. The combination of technologies, such as microfluidics for moving liquids between tiny chambers on specialized diagnostic chips and nanotechnology-enabled methodologies for sensing molecules, are leading to tools for cheaply and rapidly making thousands of molecular measurements on single drops of blood and other biological fluids such as saliva.

By combining these kinds of tools with low-cost genomic sequencing, physicians will have new means for detecting, monitoring, and making decisions on how to treat cancer and other diseases. Instead of measuring one or two proteins, it will become possible to multiplex thousands of measurements to characterize even the subtly different disease pathways that occur in individual patients. The ability to perform diagnostic measurements and also monitor the outcomes of treatments in near real time will guide physicians in their quest to personalize the selection of therapies and to choose the best time course of administration for the most effective treatment. Because FDA requirements for the approval of diagnostics are not as elaborate as for *in vivo* imaging agents or therapeutics, diagnosis and treatment monitoring are areas of nanomedicine that will most likely be the first to provide "game changing" technologies for managing human diseases.

Another exciting trajectory in nanomedicine is the development of more sensitive and selective imaging methodologies. Imaging agents based on newly designed nanoparticles can reveal the presence of cancer cells far more readily than can molecular imaging agents that have been state of the art. The ability to fabricate nanostructures that act cooperatively to enhance the sensitivity of MRI and other imaging methods, combined with targeted delivery of these assemblies to increase concentrations at sites of disease, are making medical imaging ever more capable. These new imaging techniques go beyond anatomy to the molecules involved in disease. For example, researchers working on targeted nanoparticle-based imaging techniques expect that in the future, these new methods will enable them to scan the entire body at once for the presence of cancer that has spread from a primary tumor. Even more importantly, these nanoparticle technologies will enable physicians to classify the molecular signatures of each tumor, which is the sort of information they need to tailor therapeutic regimens.

Yet another promising direction in nanomedicine for the next decade is the development of new therapeutics that target diseased cells and tissue in more precise fashions. Medicines with such selectivity should bring with them far fewer side effects. For example, RNA interference refers to the use of small RNA molecules that can selectively inhibit the production of proteins in a very selective manner. The scientists who unraveled the molecular basis of this phenomenon shared the 2006 Nobel Prize for Medicine or Physiology. Nanotechnology now is playing a significant role in enabling RNA interference-based therapeutics for cancer treatments. By attaching these RNA molecules to nanoparticles designed to seek out and latch onto melanoma tumor cells, researchers have shown they can inhibit the production of a

particular protein in a patient's cancer cells. Since RNA interference can be exploited to attack virtually any disease-associated protein, this phenomenon represents a therapeutic strategy that should have broad clinical implications. It should be pointed out that because of the significant amount of pre-approval studies required by the FDA, developing nanomedicines such as RNA-nanoparticle complexes is the most costly and most long-term endeavor in the nanomedicine context.

Beyond Steel: High Strength Materials

The White House press release in 2000 envisioned development of "materials that are 10 times stronger than steel, but a fraction of the weight for making all kinds of land, sea, air and space vehicles lighter and more fuel efficient." By that year, measurements of the stiffness and strength of CNTs, which are carbon atoms arranged in a chicken-wire-like lattice (graphene) and rolled up into minuscule seamless tubes, inspired politicians and engineers alike to imagine new high-strength, but low-weight materials. Single-walled carbon nanotubes (SWNTs) are nearly 10 times as strong as steel. A more important property of a material when it comes to applications needing lightweight structural materials is the ratio of strength to weight. For CNTs, when measured along their long axis, that ratio is about 20 times that of steel.

Reducing the weight of structural materials offers significant payoffs. A study released in 2002 by the National Academies, entitled *Effectiveness and Impact of Corporate Average Fuel Economy (CAFÉ) Standards,*[35] found that reducing the weight of a vehicle by 20 percent percent results in a 15 percent percent reduction in fuel consumption. Given the much greater strength-to-weight ratio of SWNTs compared to steel, nanostructured composite materials could allow designers to reduce the weight of structural components without compromising stiffness and other properties needed to maintain passenger safety.

It did not take long before an obstacle to realizing the technological promise of CNTs became evident. Conventional methods of fabricating fiber-reinforced composite materials depend on the ability to disperse fibers into uniform composites that are simultaneously stiff, strong, and *tough.* (Toughness is a measure of a material's resistance to crack propagation). For CNTs, which in this context constitute novel and unprecedentedly small fibers, the critical challenges included uniformly dispersing the nanotubes within a polymer or other matrix to enable sufficiently dense loadings and tailoring interfaces to control adhesion with the matrix to assure effective distribution of stresses. Engineering the surfaces of carbon nanotubes is particularly challenging because their surfaces are relatively inert and surface treatments to improve adhesion can damage them.

In the last few years, a way has been found to completely sidestep the loading problem, at least in some applications. With a novel process, materials scientists and engineer have managed to make and spin nanotubes directly into fibers and even cloth. CNT-based composites made with such starting materials are now being developed and tested for a wide variety of applications (See the case study on Nanocomp, page 34). Early applications address limited markets such as strong lightweight electrical wiring for satellites and aircraft, where weight reduction is crucial. However, the manufacturing processes appear to be scalable to large volumes at much lower cost, potentially making the material practical for large vehicles.

35. www.nap.edu/openbook.php?isbn=0309076013

This is merely a glimpse of what could become possible with advanced composite materials. Nature's own nanocomposites, among them bone, shell, and wood, are simultaneously strong, light, and tough, even though they are composed from the somewhat limited set of materials available through biological evolution. The secret to these enviable combined properties is that natural materials are organized hierarchically at the nano, micro, and larger scales to achieve orders-of-magnitude increases in, for example, strength, and toughness compared to their constituent phases. Wood is a cellular composite with four levels of structure spanning the molecular to the macro scale. Its stiffness and strength per unit weight are comparable to steel, and its toughness is 10 times that of a conventional fiber-reinforced composite with a comparable loading of fibers. A challenging vision for the next 10 and 20 years is to emulate proven natural designs in manufacturable architectures where the ultimate properties of engineered nanoconstituents can be fully realized and enhanced.

Energy and the Environment

The world demand for energy is expected to double by the year 2050. The primary challenge is not how to meet this demand, but how to do so in an environmentally acceptable manner. This is where nanomaterials will come in; they will play a large role in creating sustainable, environmentally acceptable energy and fuels. Nanostructured materials already underlie significant advances in energy storage, transmission, and transformation in the form of, for example, lithium ion batteries, heat pumps, and photovoltaic cells, respectively.

Probably the most crosscutting area of science and technology for the energy and environmental sectors is catalysis, a field based on structures and phenomena at the nanoscale. Although catalysis is already a commercial success story in numerous energy and environmental applications—notably in the efficient catalytic "cracking" of petroleum into the smaller molecules of liquid fuels and in the catalytic converters on automobiles—there remains a critical need to develop new catalytic materials. Catalysts have been described in a NSF report as "the engines that power the world at the nanometer length scale."[36] Additionally, that report goes on to provide a grand challenge for catalysis scientists and engineers: "To control the composition and structure of catalytic materials over length scales from one nanometer to one micron to provide catalytic materials that accurately and efficiently control reaction pathways."

Future clean energy technologies such as the conversion of sunlight to fuels, fuels from biomass, and the splitting of water into hydrogen and oxygen will only be achievable via breakthroughs in catalysis. At this time, the understanding of how light interacts with catalytic materials lags significantly behind the knowledge on the interactions of molecules with catalytic materials. Advances in the fundamental physics and chemistry underlying catalysis, along with molecular self-assembly methods where cleverly designed precursors automatically assemble into catalytic nanostructures, should enable the design and fabrication of photocatalysts with improved efficiency in light absorption and/or conversion.

There is a history of successfully developing catalytic materials into commercial processes that have had large impacts on the energy and fuels sectors. New approaches with nanomaterials and systems that include them are likely to follow suit. Investments in nano-based catalytic science and technology are

36. From NSF Workshop Report on "Future Directions in Catalysis: Structures that Function on the Nanoscale," NSF Headquarters, Arlington, VA, June 19-20, 2003, Davis, M., Chair, Tilley, Don, Co-Chair.

likely to have major payoffs because the pathways and associated risks for translation of fundamental discoveries in catalysis into commercial technology are established. According to a DOE Basic Energy Sciences Workshop, "Basic Research Needs: Catalysis for Energy,"[37] held in 2007, a 10-year grand challenge for realizing the full potential of catalysis for energy applications is the development of a profound understanding of catalytic transformations. That knowledge will become the foundation for designing and fabricating future catalysts with atom-by-atom precision and for converting reactants to products with molecular precision. Addressing this grand challenge should be a major priority of the NNI in the coming decade.

National Security

The events of 9/11, deaths from the subsequent anthrax attack, threats to encryption and cybersecurity, and the evolving complex socio-political climate have created a new context for national security during the last decade. During the next decade, nanotechnology has the potential to improve national security in many respects.

In strictly military contexts, developments in nanotechnology are expected to provide soldiers with smart, responsive, lightweight field technologies like adaptive camouflage, self-healing armor, wound-healing medicines, self-decontaminating clothing, and sensor and communication systems to allow complete situational awareness. Nanostructured quantum computing architectures based on control of the state of electron spin are envisioned to enable new levels of encryption and cybersecurity.

Nanotechnology development also is intimately linked with other security issues, among them energy production, our dependence on foreign oil and other resources, the global environment, and world health. All of these have security implications. Consider water. Scarcity of this fundamental resource could lead to international conflicts, and the availability of clean water is crucial to world health. Nanotechnologies are expected to enable the development of more efficient and less expensive ways to purify water. Specific technologies in this context could include nanostructured adsorbents, decontaminants, and filters.

Another way that nanotechnology is coupled to national security is in the detection of radiological, explosive, chemical, and biological agents. Sensitive, fast, stable sensors capable of operation in complex environments are needed for detection of a spectrum of potential threats. It is generally argued that nanoscale sensors, such as nanowire-based field effect transistors, are inherently more sensitive than microscale systems. Taking a cue from the immune system, which can rapidly detect tiny quantities of a specific molecule, researchers have begun integrating engineered biological nanocomponents such as antibodies, nucleic acids, and proteins with nanoscale sensors to develop devices that can detect specific threats. Some of the challenges of threat detection are shared with those of medical diagnostic systems such as detection of tiny amounts of analytes, multiplexing to avoid false positives, and simplicity of operation. During the next decade, it is likely that some nanotechnology strategies under current development for biological assays will also contribute to national defense.

37. www.er.doe.gov/bes/reports/files/CAT_rpt.pdf

A Vision for the Next 10 Years

In its first 10 years, the NNI has promoted progress on scientific problems of great importance to society. It has increased dramatically the investment in instrumentation, research infrastructure, and expertise. Looking forward 10 years, the NNAP sees a program that builds on these strengths. Progress must continue along lines of research such as those sketched above, but new avenues of investigation will spring up based on changing societal needs and unpredicted discoveries of a transformative and revolutionary nature. A vibrant and effective NNI will have the following attributes:

- ***Basic research will remain a critical component of the research portfolio***. NNI will continue to provide an organizational structure that promotes crosscutting research that stands to enhance our economic competitiveness. New fundamental discoveries will continue to refresh our ideas of what is possible and provide the foundation for new initiatives.
- ***While basic research continues, there will be increasing focus on integration of components and processes that lead to commercialization.*** For example, integration of nanotechnology-enabled diagnosis, imaging, and therapy will provide superior new methodologies for the management of cancer. Low-cost, sensitive, rapid diagnostics combined with whole-body imaging will allow earlier detection of cancer. Potent and selective therapies will be matched to each patient's disease characteristics and in vivo diagnostics and imaging will guide the course of treatment. Research within the auspices of NNI, coordinated with other appropriate research initiatives, will strive to tightly integrate advances in nanotechnology into an individualized cancer management strategy.
- ***The NNI will play a key role in several Signature Initiatives leveraging targeted interagency efforts to address grand challenges.*** The FY 2011 budget accommodates three Signature Initiative platforms for nanoscience and nanotechnology: Nanotechnology Applications for Solar Energy, Sustainable Nanomanufacturing, and Nanoelectronics for 2020 and Beyond. These and other bold initiatives will be chosen for their potential to improve quality of life, protect the environment, create jobs, and engage a new generation of scientists and engineers. Among some of the other Signature Initiatives on which the NNI could partner with industry, academia, and the relevant agencies are regenerative medicine, catalysis, food safety, and threat detection. These initiatives, complemented by a vibrant educational program which focuses on the potential of nanotechnology to help solve societal problems, will excite the imaginations of young people and draw the next generation of scientists and engineers into the field. For example, a new Signature Initiative to push catalysis forward may make possible the efficient splitting of water into hydrogen (fuel) and oxygen, or the use of carbon dioxide as a chemical feedstock. Translating such advances into industrial scale processes will be accelerated if the NNI continues to fund research on scientific issues critical to scale up.
- ***The balance of NNI programs will continue to evolve.*** In the coming years, for example, there will be a stronger focus on fundamental issues related to EHS. What are the structural and chemical features of nanoparticles that determine transport through, concentration in, and interactions with the human body? The effort to address those questions will be coordinated across NIH, NIST, EPA, and other relevant agencies. The increased focus on integration and system

demonstrations will demand an increased focus on research that is relevant to assembly and eventual manufacture of such systems. Exploration of relatively simple self-assembly processes that are suitable for batch fabrication of relatively simple systems will be supplemented by research into fabrication of complex structures and systems with many interacting nanoscale components. Research will therefore focus on increasingly sophisticated processes and systems for directed and templated self-assembly. There will also be a component of manufacturing research focused on new processes for precision patterning, looking beyond the optical and e-beam lithographic processes driven by the microelectronics industry. Novel means of fabrication with ever finer precision should be the focus of new investments in nanomanufacturing, including modeling and simulation, metrology tools, and the merging of self-assembly with lithography to achieve large-scale predictable placement of nanoscale components.

Acknowledgments

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Appendix A: Statement of Task

President's Council of Advisors on Science and Technology

Review of the National Nanotechnology Initiative

The 21st Century Nanotechnology Research and Development Act of 2003 (Public Law 108-153) calls for a National Nanotechnology Advisory Panel to periodically review the Federal nanotechnology research and development program known as the National Nanotechnology Initiative. The President's Council of Advisors on Science and Technology is designated by Executive Order to serve as the NNAP.

The study intends to answer the following questions from The 21st Century Nanotechnology Research and Development Act of 2003 (Public Law 108-153):

1. What are the trends and developments in nanotechnology science and engineering, as they relate to the NNI and generally?
2. Please describe NNI's progress in the last two years in implementing the NNI Program.
3. Does the NNI Program need to be revised? If so, how?
4. Is the balance correct among the components of the NNI Program, including funding levels for the program component areas?
5. Have the component areas, priorities, and technical goals helped to maintain U.S. leadership in nanotechnology?
6. Has the management, coordination, implementation, and activities of the program being been carried out appropriately over the last two years? How could improvements be made?
7. Have societal, ethical, legal, environmental, and workforce concerns been adequately addressed by the Program during the last two years?

The study will address additional questions:

8. What should be the goals, priorities and platforms for the NNI for the next five years in science, biomedical research, nano-renewables, and nano-electronics?

Environment, Health, and Safety (EHS):

9. Has NNI established an acceptable strategy to address appropriate EHS priorities?
    - Is it effective?
    - Is it filling knowledge gaps?
    - Does it have an implementation and review plan?
    - Does it support evidence-informed decision making?
10. Is NNI appropriately invested in EHS research to address the priorities?

11. Has NNI implemented an approach toward achieving the goals of the strategic plan that leverages the strengths of Federal agencies?
    - Have experts and other stakeholders outside the Federal Government been engaged effectively in addressing nano-EHS issues?
    - Have experts had input to the research strategy?
    - Have industry, consumers and other stakeholders been engaged in identifying and addressing EHS issues?
    - Have State agencies been engaged in addressing EHS issues?
12. Has collaboration between Federal agencies been effective at addressing nano-EHS issues?
    - Have cross-agency actions been coordinated or conflicting?
    - Have efforts to ensure interagency collaboration added value to the NNI?
    - Is there clear evidence of cross-agency collaboration having a significant impact on agency decisions and strategies?
13. Have Federal agencies collaborated effectively with international partners on addressing nano-EHS issues?
    - Is there a clear and substantial awareness of international developments and actions?
    - Are Federal agencies engaged with international partners, and are these engagements coordinated across the Federal Government?
    - Is there clear evidence for the United States influencing international developments, and benefiting from international collaborations?
14. Are there mechanisms in place to ensure research into the EHS implications of nanotechnology leads to evidence-informed decision making?
    - Is there a clear link between research and policy?
    - Is research targeted to providing information regulators need to make informed decisions?
    - Are there mechanisms to coordinate regulatory actions on nanotechnology across Federal agencies?

Nanotechnology Outputs

15. What are the trends and developments in nanotechnology science and engineering and product introduction since 2008 (the last PCAST review): in the United States, internationally, and at the level of individual States?
16. Is the United States the leader, in what areas, and by what metrics?
17. Has progress been made since the last review in the transfer of science to products and processes, in technology transfer, and in the development of enabling standards?

18. Does an adequate science base to facilitate transfer of nanotechnology exist, if so in what areas, if not where are the gaps?

19. Has progress been made since the last review in the transfer of science to products and processes, in technology transfer, and in the development of enabling standards?

Program Management

20. Has appropriate progress been made since the last PCAST review in managing and implementing the program?
    - Has an appropriate strategic plan been developed for NNI broadly, and does it include societal, ethical, legal and workforce objectives?
    - Do clear objectives exist to achieve the goals of the strategic plan?
    - Is the NNI appropriately balanced with regard to the components of the Program, including funding levels for the program component areas?
    - What is the status of program management as it relates to coordination and implementation of efforts across NNI?

21. Is there a need to modify the strategic plan that was in place at the last review to reflect changing priorities or developments in the NNI?

22. Has the investment in equipment infrastructure been adequate, and has there been some larger coordination among agencies in developing that infrastructure?

23. Have the investments in education and communication to the public been effective?
    - What has been learned?
    - What more should be done?

24. If the societal, ethical, legal and workforce objectives have not been well integrated into the program, how should NNI proceed in the future?

25. What is the status of program management as it relates to coordination and implementation of efforts across NNI?
    - Are there areas that require greater emphasis and coordination?

26. Does the NNI have the ability to quickly respond and adapt to new scientific/technological advances?

27. What is the impact of NNI beyond the creation of publications and patents?

Appendix B: Contributors to the Development of the Statement of Task

Individual PCAST members

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Appendix D: Study Design—Review of the National Nanotechnology Initiative

A Statement of Task was developed (see Appendix A)

- Requirements from Public Law 108-153 were included.
- Interviews (see Appendix B) were conducted.

Working Group members were selected and vetted.

Working Group members sorted into teams to complete the study:

- Program management
- Environment, health, and safety
- Outputs of NNI
- Vision for the future of nanotechnology

Weekly Working Group conference calls were held for administrative purposes to refine and conduct the review

Two in-person meetings were held for preparatory purposes to gather expert opinions (see Appendix C).

- January 19–20, 2010, Washington, DC.
- February 18–19, 2010, Palo Alto, CA.

All invited experts were asked to complete a survey comprised of questions from the Statement of Task.

Additional data gathering and analysis was conducted at the request of the Working Group by analysts at the Science and Technology Policy Institute.

Recommendations were developed and a study report was written by Working Group members.

The NNI review report and its recommendations were presented to PCAST on March 12, 2010.

Appendix E: Federal Agencies Participating in the NNI

Federal Agencies with Budgets Dedicated to Nanotechnology Research and Development

Consumer Product Safety Commission (CPSC) Department of Defense (DOD)

Department of Energy (DOE)

Department of Homeland Security (DHS)

Department of Justice (DOJ)

Department of Transportation (DOT, including the Federal Highway Administration, FHWA)

Environmental Protection Agency (EPA)

Food and Drug Administration (FDA, Department of Health and Human Services)

Forest Service (FS, Department of Agriculture)

National Aeronautics and Space Administration (NASA)

National Institute for Occupational Safety and Health (NIOSH, Department of Health and Human Services/Centers for Disease Control and Prevention)

National Institute of Food and Agriculture (NIFA, Department of Agriculture)[38]

National Institutes of Health (NIH, Department of Health and Human Services)

National Institute of Standards and Technology (NIST, Department of Commerce)

National Science Foundation (NSF)

Other participating agencies

Bureau of Industry and Security (BIS, Department of Commerce)

Department of Education (DOEd)

Department of Labor (DOL)

Department of State (DOS)

Department of the Treasury (DOTreas)

Director of National Intelligence (DNI)

International Trade Commission (ITC)

Nuclear Regulatory Commission (NRC)

U.S. Geological Survey (USGS, Department of the Interior)

U.S. Patent and Trademark Office (USPTO, Department of Commerce)

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38. Section 7511 of the Food, Conservation, and Energy Act of 2008 (FCEA) established within the Department of Agriculture the National Institute of Food and Agriculture (NIFA) and transferred all authorities of the Cooperative State Research, Education, and Extension Service (CSREES) to NIFA not later than October 1, 2009.

Appendix F: List of Acronyms

CBI	confidential business information
CNT	carbon nanotubes
CPSC	Consumer Products Safety Commission
CR-BSI	catheter-related blood stream infections
DOD	Department of Defense
DOE	Department of Energy
EHS	environment, health, and safety
EU27	27 nations of the European Union
FDA	Food and Drug Administration
FET	field effect transistor
GAO	Government Accountability Office
GDP	gross domestic product
GNP	gross national product
ICON	International Council on Nanotechnology
IND	Investigational New Drug Application
LAD	Luer-activated device
M&A	mergers and acquisitions
MRSEC	Materials Research Science and Engineering Centers
NCI	National Cancer Institute
NEHI	Nanotechnology, Environmental, and Health Implications
NIEHS	National Institute of Environmental Health Sciences
NIH	National Institutes of Health
NIOSH	National Institute for Occupational Health and Safety
NISE	Nanoscale Informal Science Education
NIST	National Institute of Standards and Technology
NNAP	National Nanotechnology Advisory Panel
NNCO	National Nanotechnology Coordination Office
NNI	National Nanotechnology Initiative

NRC	National Research Council
NRI	Nanoelectronics Research Initiative
NSEC	National Science and Engineering Centers
NSET	Nanoscale Science, Engineering, and Technology Subcommittee of the NSTC
NSF	National Science Foundation
NSTC	National Science and Technology Council
OECD	Organisation for Economic Co-operation and Development
OMB	Office of Management and Budget
OSTP	Office of Science and Technology Policy
PCA	Program Component Area
PCAST	President's Council of Advisors on Science and Technology
R&D	research and development
SBIR	Small Business Innovation Research
SOT	Statement of Task
STTR	Small Business Technology Transfer
SWCNT	single-walled carbon nanotube
TIP	Technology Innovation Program
VC	venture capital